RIGEL MEDICAL

Innovating Together

RIGEL UNI-SIM

vital signs simulator

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Instruction Manual
370A564 Revision 3.2

Rigel Medical 24 Month Warranty Statement

Rigel Medical provides a standard 12-month manufacturer's warranty against breakdown during normal use. This warranty can be upgraded to a 24-month warranty (terms and conditions apply*). Problems caused through misuse, damage, fair wear & tear, consumables and accessories are excluded from standard warranty. Such components found to be being used in excess of their manufacturer's operating recommendations are also excluded. Shipping to an authorised service centre is the responsibility of the sender.

*Terms and Conditions of 24 Month Warranty

The Rigel product must be registered with Rigel Medical within 30 days of purchase to be eligible for the extended 24-month warranty. Instruments must be returned to an authorised service centre complete with proof of purchase within 13 months of purchase for calibration at the current rate. Any items returned for calibration outside of the 13 month period stated above may not be eligible for the second 12 month section of warranty. The second 12 month section of the warranty begins at the expiry of the initial 12 month period, not when the unit is calibrated.

Details correct at time of going to print. The manufacturer retains the right to make amendments to the above terms and conditions without prior notice.

Calibration Statement

The Rigel Uni-SIM Vital Signs Simulator is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels; therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

Experience has indicated that the calibration of this instrument in not effected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 12 month interval from the first date the unit is placed in to service.

Date received into service; / / .

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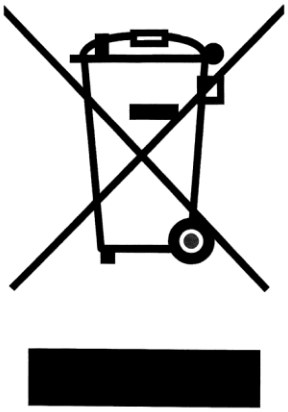
Due to a policy of continuous development the SEAWARD GROUP reserves the right to alter the equipment specification and description outlined in this publication without prior notice and no part of this publication shall be deemed to be part of any contract for the equipment unless specifically referred to as an inclusion within such contract.

Disposal of old product



The Rigel Uni-SIM Vital Signs Simulator has been designed and manufactured with high quality materials and components, which can be recycled and reused.

When this symbol is attached to a product it means the product is covered by the European Directive **2012/19/EC.**

Please familiarise yourself with the appropriate local separate collection system for electrical and electronic products or contact your local supplier for further information.

Please dispose of this product according to local regulations. Do not dispose of this product along with normal waste material. By offering your old products for recycling, you will help prevent potential negative consequences for the environment and human health.

Certificate of Conformity

This product is manufactured by: Seaward Electronic Ltd, Bracken Hill, South West Industrial Estate, Peterlee, County Durham, SR8 2SW, UK

Statement of Conformity

As the manufacturer of the apparatus listed, declare under our sole responsibility that the product:

Rigel Uni-SIM Vital Signs Simulator

To which the declaration relates are in conformity with the relevant clauses of the following standard:

BS EN 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

BS EN 61326 - Electrical equipment for measurement, control, and laboratory use - EMC requirements.

Performance: The instrument operates within specification when used under the conditions in the above standards EMC and Safety Standards.

The product identified above conforms to the requirements of Council Directive **2004/108/EC** and **2006/95/EC**.

This Conformity is indicated by the symbol CE, i.e. “Conformité Européenne”

Seaward Electronic Ltd. is registered under **BS EN ISO9001:2008** Certificate No.: Q05356.

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User Notes

These operating instructions are intended for the use of adequately trained personnel.

The following symbols are used in these operating instructions and on the Rigel UNI-SIM.

Warning of electrical danger!
Indicates instructions must be followed to avoid danger to persons.

Important, follow the documentation! This symbol indicates that the operating instructions must be adhered to in order to avoid danger.

The UNI-SIM is supplied with a mains power supply unit. The use of any other power supply unit may cause damage to the equipment and may result in a hazard to the user.

If the UNI-SIM is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

1 Introduction

The new Rigel UNI-SiM is the only simulator of its type which enables medical device engineers to quickly, easily and accurately undertake NIBP, SpO_2, ECG, temperature, IBP and respiration functionality tests simultaneously using a single portable instrument.

The battery powered vital signs simulator reduces the time taken to test the correct performance of a wide range of medical devices and equipment used in hospitals, operating theatres and other facilities.

It utilises the full synchronised functionality of Rigel's BP-Sim and SP-Sim as well as a comprehensive patient simulator (ECG, invasive blood pressure, respiration and temperature) to cut simulation times and deliver cost saving benefits – engineers no longer need to use a variety of different instruments for testing these functions separately.

Whilst the instrument incorporates a range of custom settings that include a variety of paediatric and adult NIBP pressures, pulse volume adjustments, heart rate and manufacturer-specific O-curves, the UNI-SiM can be fully customisable to meet specific performance test conditions.

The Rigel UNI-SiM also utilises new and advanced technologies to maximise the accuracy of each simulation such as using both electronic and optical SPO2 simulation methods in a single test setup and manufacturer specific simulation curves during the NIBP simulation, reducing uncertainties thus improving the test time.

Featuring Bluetooth connectivity, simulation test results can be stored within the instrument and printed wirelessly to the rugged battery operated Elite Test n Tag printer.

Traceability is improved as information can be downloaded into Med-eBase - the easy-to-use asset management software. This enables the user to store and manage test results, email html test certificates to clients and schedule new work orders, which can then be fully uploaded into a large onboard memory.

The compact, lightweight design and long life battery power of the UNI-SiM reduces downtime between tests, making the instrument practical and highly portable for multi-site use. It features easy-to-follow menu driven instructions for ease of operation and test control of all required electrical safety tests in manual, semi automatic or fully automatic test modes.

A large internal memory facilitates the storage of test results for safety audit and traceability purposes. In addition, as well as storing the results of electrical tests, there is also the ability to record user defined inspections and measurements from other equipment such as SpO_2, NIBP, ECG and other electro medical patient equipment.

The new Rigel UNI-SIM forms part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical, part of the Seaward Group.

1.1 Rigel UNI-SIM Design Philosophy

The UNI-SIM has been designed to address the increasing demand for smaller more comprehensive test equipment within the Healthcare Industry.

The challenge was to combine the functionality of three separate simulators into a single hand-held device without compromising on the accuracy and functionality.

Today's industry demands test equipment that can save time and cost, thus offering greater flexibility. These factors have all been taken into account during the development of the UNI-SIM.

The test capabilities and functionality exceed that of most individual simulators yet the instrument is only a fraction of the size and weight of .

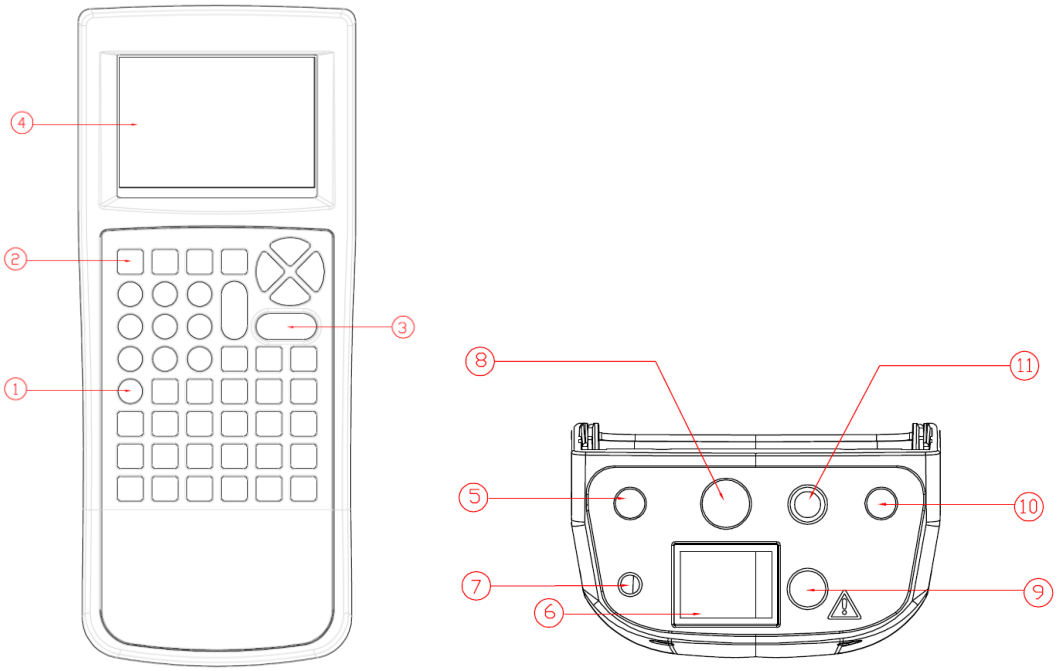
No other single simulator on the market is able to simulate all six vital signs like the UNI-SIM does. Housed in a hand-held enclosure, the UNI-SIM offers the test capabilities equal to most bench mounted versions, a simple user interface, large internal memory, Bluetooth communication, asset management facilities, user configurable Performance Tests and more.

We believe that the new UNI-SIM is set to become the new standard in vital signs performance Testing.

1.2 Key Features

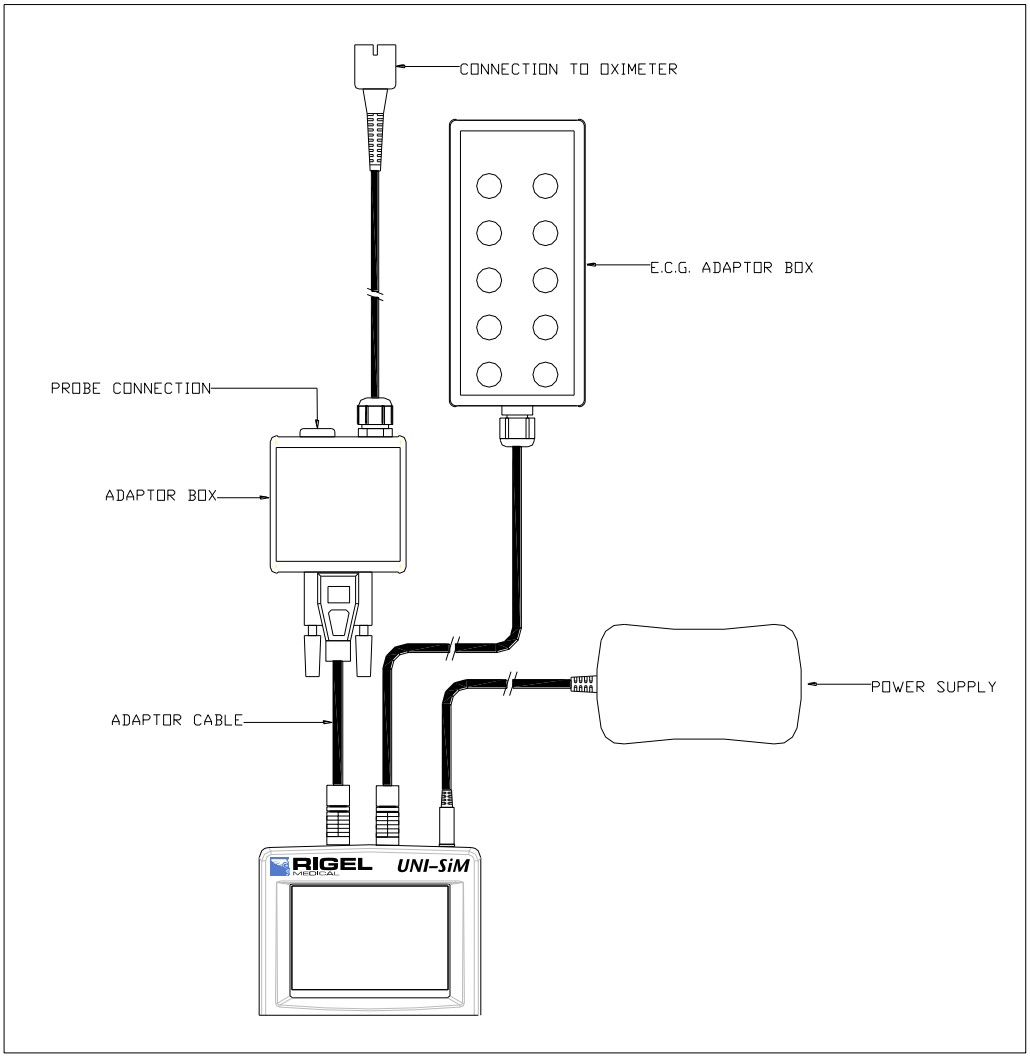
- **Portable and Lightweight** - Ideal for field service technicians and in-situ testing of NIBP performance
- **Battery Operated** - For convenient and fast testing without mains power
- **Manufacturer O-curves** - To ensure accurate simulations across a wide range of different brands and models
- **Internal Pump** - Easy testing of pneumatic leaks and over-pressure valves
- **Manufacturer R-curves** - To ensure accurate simulations across a wide range of different brands of SPO2 probes
- **Prepared for PPM Protocols** - Configured for automatic performance testing of a variety of parameters
- **Full Keyboard** - Easy data capturing and asset management
- **Intuitive User Interface** - Fast and easy navigation using graphics display
- **Graphics Display** - Allowing real-time display of pressure curves and simulation data
- **Bluetooth Communication** - PC download and future field upgrades
- **Web Updates** - Enjoy easy updates through our website to benefit from the latest features

1.3 Interfaces



1) Alpha Numeric keyboard, Up / Down and Left / Right cursor control.
2) 4 Programmable soft keys below display
3) Colour Green / Red for start /stop and On / Off
4) Full graphic Monochrone LCD, blue with white backlit, 1/4 VGA
5) Temperature simulation output
6) NIBP simulation / Pneumatic interface connector
7) Power Supply inlet
8) 12 lead ECG simulation output
9) SPO2 simulation output
10) IBP simulation output
11) High level ECG simulation output

1.4 Connecting the accessories



The Rigel UNI-SIM is supplied in two parts. The basic unit (370A930) and the accessory pack (370A931), see below for a list of items included in the accessory pack.

1.5 Rigel UNI-SIM accessory pack includes (pn 370A931):

- ECG interconnect module 370A688
- 10 ECG adaptor studs 274A725
- Universal Power Supply (230/110V) 370A010
- UNI-SiM carry case 71G098
- 5-pc tubing adaptor set 370A005
- Adaptor connect cable 370W505
- Instruction manual 370A564
- Rigel utility disc 331A557
- Bluetooth USB adaptor 339A910
- Safeguard Warranty Card 74B004

1.6 Additional & Optional Accessories

For a full range of UNI-SIM accessories and cables, please visit:

http://www.rigelmedical.com/downloads/Rigel-SIM-Range-Accessory-Datasheet-Rev1-1.pdf

1.7 Test 'n Tag Compatible

The Rigel UNI-SIM is compatible with the Seaward Test 'n Tag and Elite system. Our Test 'n Tag systems allows you to print customised Thermal PASS / FAIL labels.

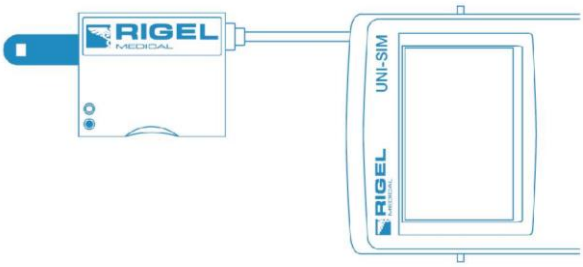
The benefits of using the Test 'n Tag printers are:

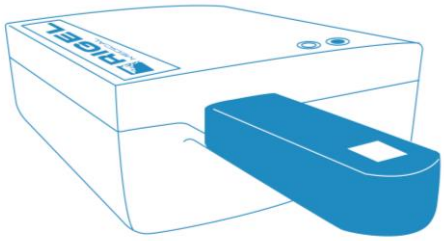
- Robust and durable labels
- Resistant to most solvents used in the medical sector
- Free opportunity to advertise your logo and company details or emergency telephone number with every item you Test 'n' Tag.
- Automatic barcode generation to provide easy use of the barcode scanner thus speeding up your test time.

The unique Test 'n' Tag label provides test status and retest due date, barcode and asset ID number, and person conducting the test. For more information on using the Test 'n Tag printer, see section 9.2.

2 Using the PULS-R optical finger with the UNI-SIM

The PULS-R optical finger is for use only with Rigel SP-SIM and UNI-SIM products





2.1 Accuracy of simulation when used with the corresponding R-curves

Resolution	Range	Repeatability*
1% steps	30 - 60%	±5%**
1% steps	60 - 90%	±3%
1% steps	90 - 100%	±1%

* Based on using the same probe and monitor setup
**Note that some monitor types might not be able to display low range sats

Operating temperature	0-40°C
Dimensions	78 x 68 x 29 mm
Finger shape	40 x 18 mm
Heart Rate	30-300 bpm
Part number	399A910

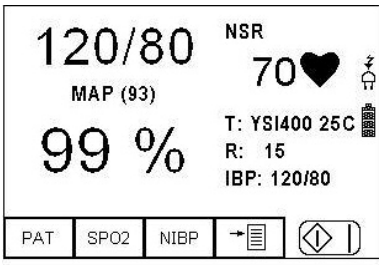
2.2 Getting started

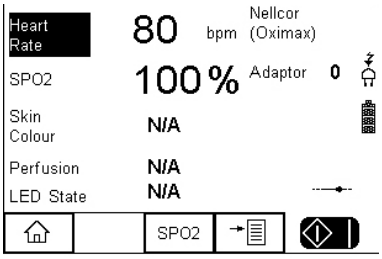
Turn on your Rigel UNI/SP-SIM by pressing and holding the green start button until you hear a “beep” and the Rigel splash screen appears.

The summary simulation screen appears displaying the settings from the previous simulation for all parameters and can be repeated by simply pressing the green start key

For both the Rigel UNI and SP- SIM the user will need to select.
SPO2 Simulation.

Image 1 of the UNI-SIM shows NIBP, SPO2, ECG, IBP, Respiration and Temperature and Image 2 shows the same for the SP-SIM.



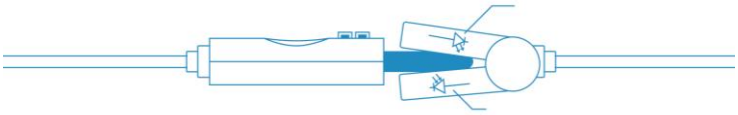


The connection between the PULS-R, the UNI/SP-SIM and the monitor is shown in the diagram using the SP02 connector lead.

2.3 Performing SP02 simulations

The connection between the PULS-R, the UNI/SP-SIM and the monitor is shown in the diagram connected to the SPO2 port on the SP-SIM/UNI-SIM' or similar text.

The correct orientation for probe place is with the LED of the probe on the top side of the PULS-R.



Parameters can be varied to validate the monitor and probe including:

- Technology. E.g.: PULS-R, Masimo, Nellcor....
- SPO2 (%) simulated
- Heart Rate

Supported Default curves:

- Beijing Choice (PULS-R)
- Criticare (PULS-R)
- GE Ohmeda Tuffsat (PULS-R)
- Masimo (PULS-R)
- Mindray (PULS-R)
- Nellcor (PULS-R)
- Nellcor OxiMax (PULS-R)
- Nihon Kohden (PULS-R)
- Nonin (PULS-R)
- Novametrix (PULS-R)
- Philips/HP (PULS-R)

To customise your own R curves please see application note 0061 Creating and uploading R Curves for UNI-SIM and SP-Sim.

2.4 Unique use of ICONS

The Rigel UNI-SIM features a hi resolution graphic back lit display which not only provides highly visible and easy to follow menu structures but also allows the user to operate the tester using intuitive icons to speed up their test routines.

Below are of some of the icons used in the Rigel UNI-SIM:

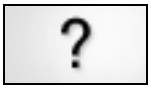
Escape

Add

Copy

Delete

Edit

 Help

Menu – List

Home

New

OK – PASS

Print

Less

Repeat

Save

Search

Settings

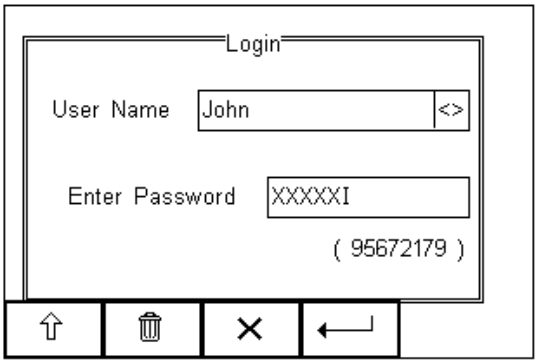
Shift

Mute

Sound

3 Logging on

When switching on the Rigel UNI-SIM, the user will be able to log-in to allow for specific default user preferences and to provide traceability of test results. To increase the security and protection of the user, a password can be set prior to using the Rigel UNI-SIM. See 8.5.3 for further details. The default password setting is OFF and the login screen will not require a password. In case a user and password are set, the tester will default to the last user / password.



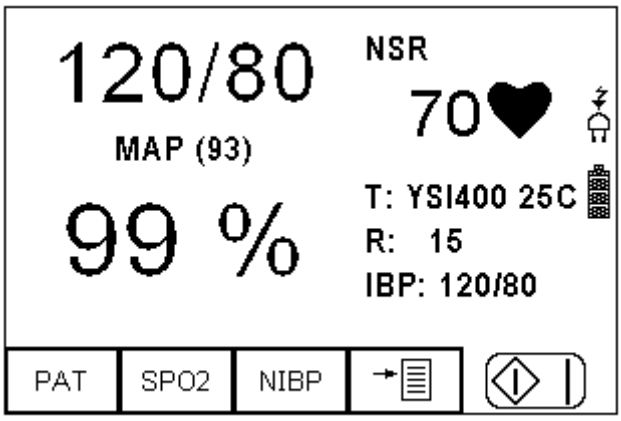
To change the user, use the drop down menu provided [<>] and select the new user. In case a password is set for the new user, please enter the password (case sensitive).

In case a password is lost and the unit is blocked, please call our helpdesk on:
+44 (0) 191 5878701 or contact your local distributor and quote the 8-digit code (shown below the password field) and the serial number of the tester. A new password will then be created. For security reasons, this new password can only be provided to the email address of the original purchaser of the device.

The Rigel UNI-SIM is designed to allow a user to customise test sequences and allow default settings. This customisation can speed up testing by providing the user with default manufacturer lists, model numbers, user text protocols, automatic printing post-text and fault menus.

4 Getting Started

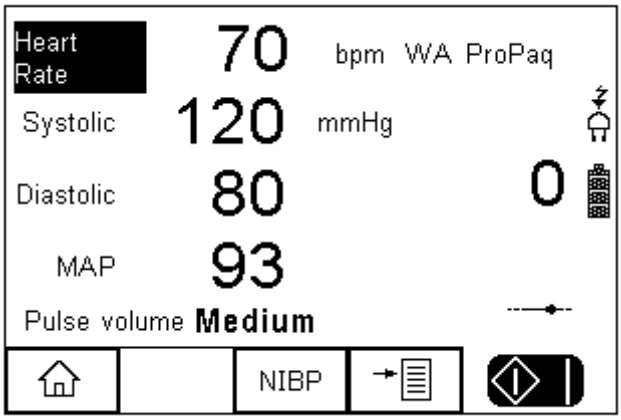
The Rigel UNI-SIM can be used as a manual simulator or an automatic simulator. Upon power-up, the user is presented with the summary simulation screen. This displays the previous simulation settings and can be repeated by simply pressing the green start key.



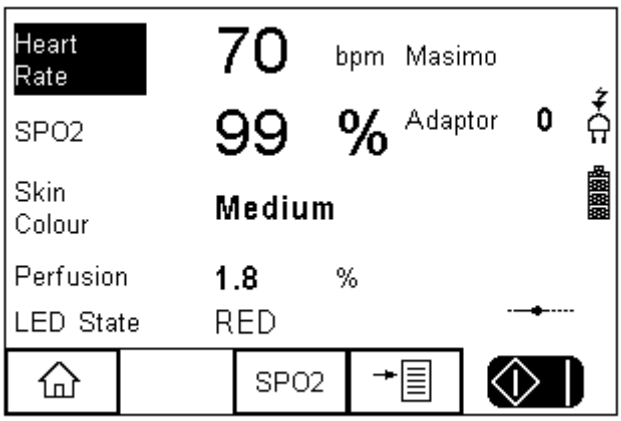
Alternatively, the user can choose between selecting a single or all of the simulation settings (ie NIBP (F3), SPO2 (F2) or PATient (F1) simulator) or entering the menu (F4) allowing for automatic testing, modifying the simulators default settings, viewing and downloading data and other user settings.

Use your UNI-SIM as a simple manual simulator from the summary screen by selecting the simulation function you want:

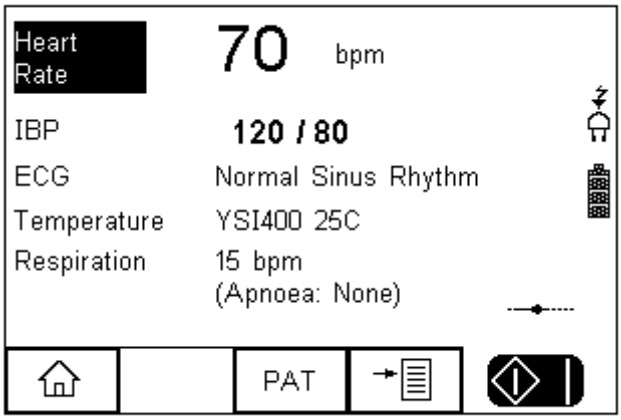
- NIBP (F3) simulate NIBP, perform a system leak test, overpressure test, static pressure test or manometer function.



- SPO2 (F2) simulate SPO2 signals, response times, artefacts and check probe performance



- PAT (F1) (full 12 lead patient simulator including ECG, Arrhythmia and performance waveforms, respiration signals, temperature simulation and invasive blood pressure simulation)



To change any of the default settings on each simulation, please refer to the relevant manual mode sections in this manual, chapter 5,6 and7.

This manual is constructed in four main parts:

1. Manual mode (see 5,6,7)
2. Setting-up your tester (see 0)
3. Automatic mode (9)
4. Data management (10,11)

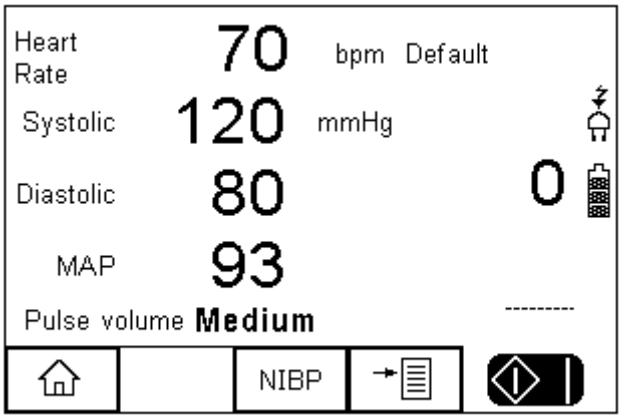
5 Manual Mode NIBP

The Manual mode provides the user with the features of testing a specific individual test and or test condition for example to test a selection of:

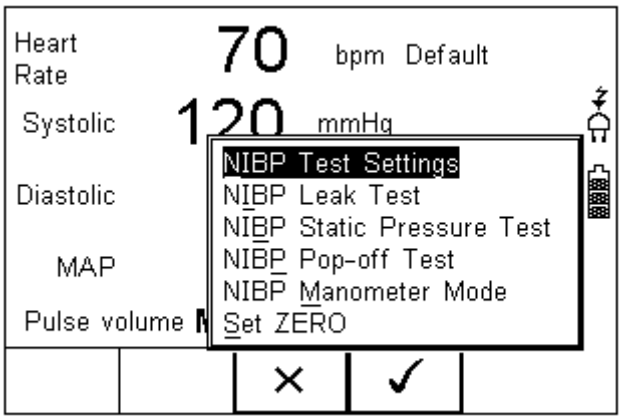
- NIBP tests
- Leak tests
- Static pressure calibration
- Pop-off valve test
- Manometer function

From the main summary screen, select the NIBP fact key (F2)

Press NIBP (F3) from the start screen;



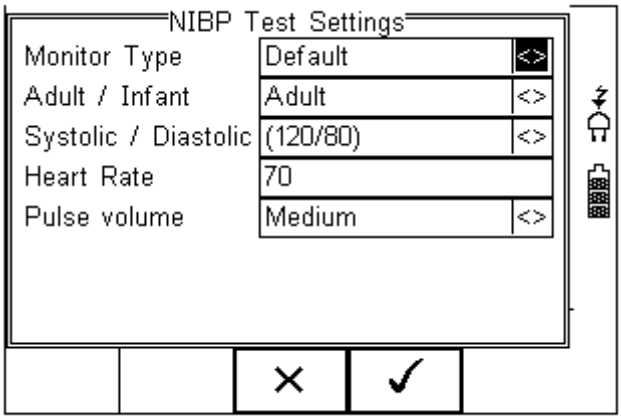
When NIBP is selected, a number of options will be available;



- NIBP Test Settings (see 5.1)
- NIBP Leak Test (See 5.2)
- NIBP Pop-off Test (see 5.4)
- NIBP Manometer Mode (see 5.5)
- Set Zero (see 5.6)

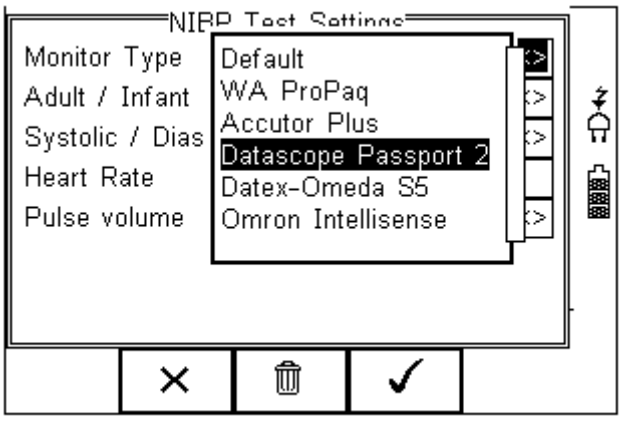
5.1 NIBP Test Settings

Use the NIBP Test Settings to setup a selection of Dynamic Pressure simulations.



Navigate using the Up & Down Keys and change each setting by using the left key.

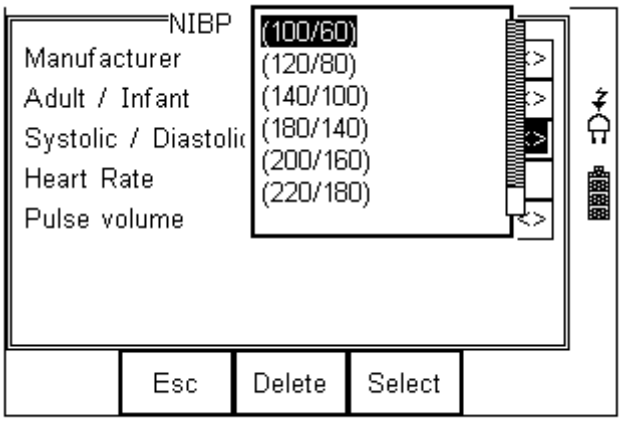
Manufacturer; Select between a default O-curve or one specific to a manufacturer, for example;



Additional manufactures will be developed and can be uploaded through new firmware revisions from our website; http://www.rigelmedical.com/downloads.asp

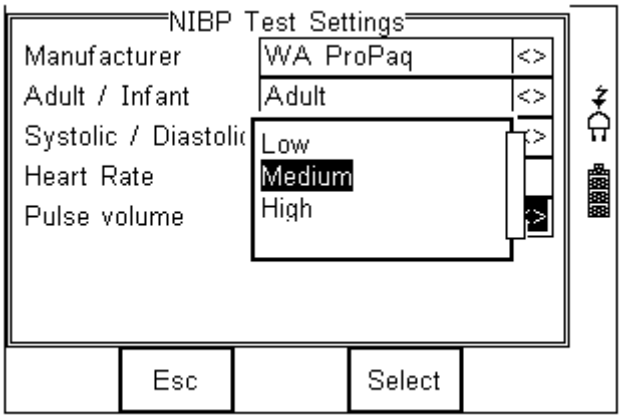
Adult / Infant; Toggle between Adult or Infant settings. Default settings such as heart rate and pulse volume will be adjusted automatically.

Systolic / Diastolic; Select a pre-set range of NIBP setting from the drop down list



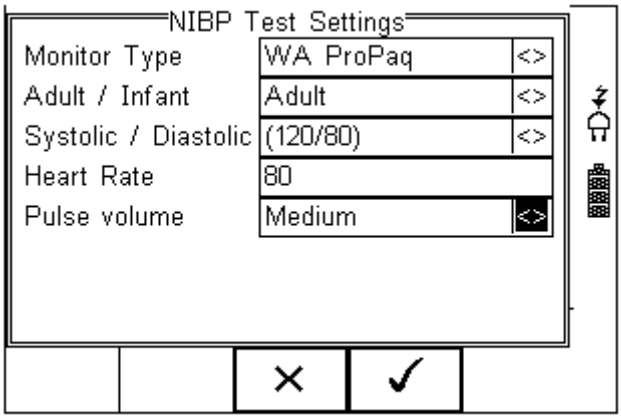
Heart Rate; Enter the required simulated heart rate

Pulse Volume: Select the required pulse strength to simulate different volume strength.



Note that the settings Low / Medium / High are not directly linked to any physiological condition

Note that High pulse volume settings can only be achieved when the UNI-SIM is connected to the mains through the correct power supply.

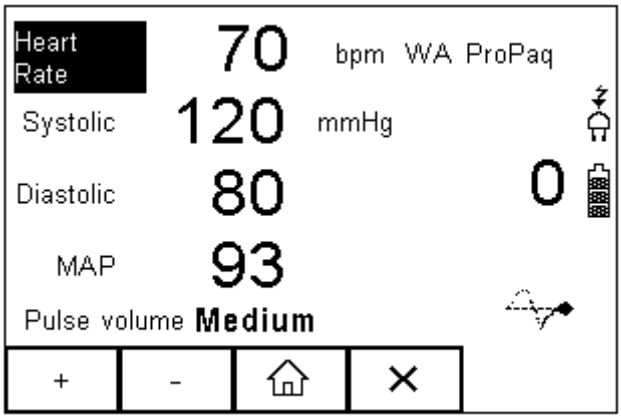


Once the selections are complete, select the ✓ (F4), to confirm the settings;

Press the Green Start key to start the simulation and close the internal valve within the UNI-SIM.

Note when the valve is not closed, the pressure within the cuff will not be contained and the monitor might go into alarm.

When the simulation is present (i.e. the internal UNI-SIM valve is closed), a “pulse” symbol will be shown;



Using the Function keys (F1-F2), and up and down arrow keys, the highlighted field (change using arrow keys) can be changed using the “+” and “-“ function keys F1 and F2.

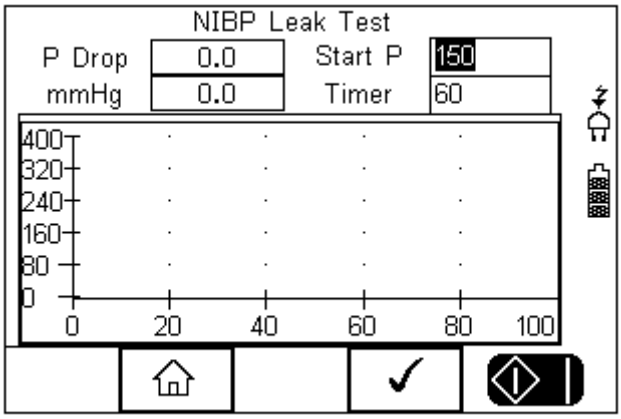
5.2 NIBP Leak Test

In the NIBP leak test, the user is able to test the pneumatic leakage within the system.

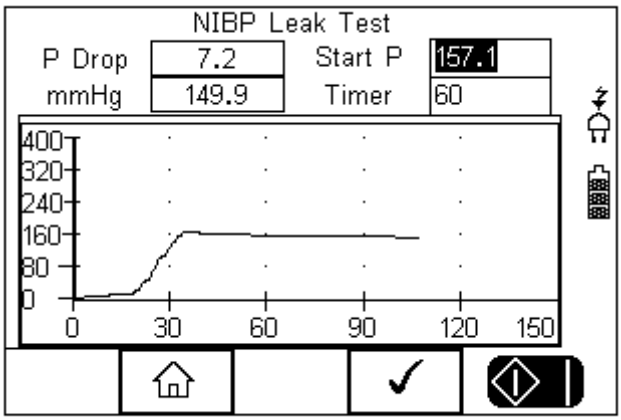
The settings available are:

- Start Pressure
- Timer (seconds)

Note: Prior to initiating the test, some NIBP monitors might have to be set to a service mode to ensure that the internal monitor valves are shut for incoming pressures. If the monitor’s internal valve is open, the leak test will not be able to pressurise the system.



The UNI-SIM will inflate the system to around the set-point. Once the system is stabilised at the set pressure, the timer will count up for the set duration. This is highlighted below:



At the end of the test, the UNI-SIM will show;

- the start pressure (i.e. 157.1 mmHg)
- the final pressure (i.e. 149.9 mmHg)
- the pressure drop over 60 seconds (i.e. 7.2 mmHg)

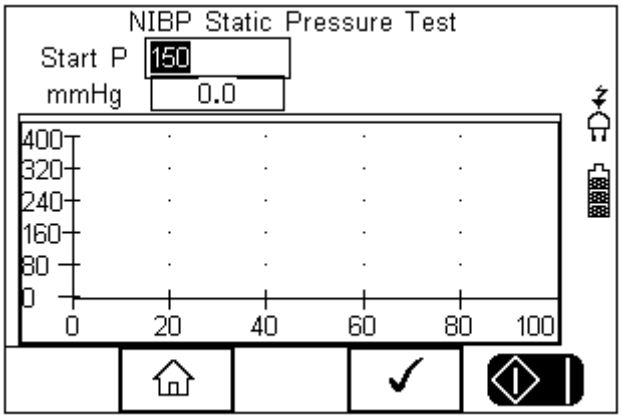
Press ✓ (F4) to repeat the test

Press ⌂ (F2) to return to start menu

5.3 Static Pressure test

The UNI-SIM is able to perform a static pressure test similar to that used in the leak test. Enter a pressure value in the UNI-SIM screen below, which will inflate the system to the set pressure. The user is then able to enter a new (higher) value for further testing.

Select the Static Pressure Test from the NIBP menu;



Press ✓ (F4) to repeat the test

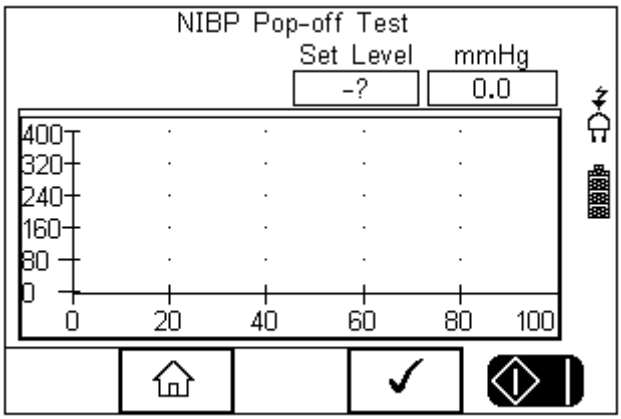
Press ⌂ (F2) to return to start menu

5.4 NIBP Pop-off Test

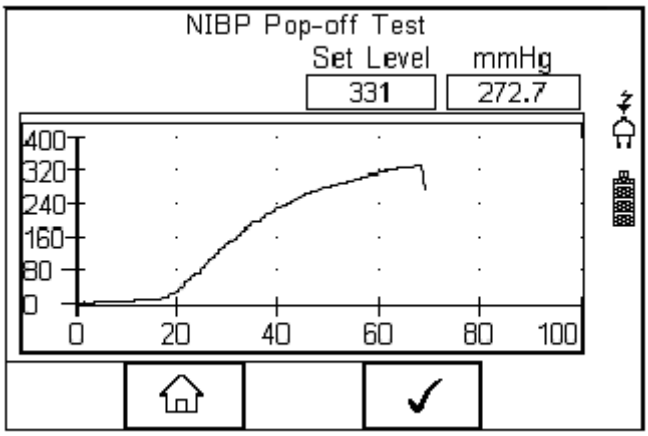
The Pop-off test allows the user to verify the correct operation of the protection valve within the NIBP monitor.

Note: Prior to initiating the test, some NIBP monitors might have to be set to a service mode to ensure that the internal monitor valves are shut for incoming pressures. If the monitor's internal valve is open, the leak test will not be able to pressurise the system.

Select the test from the NIBP menu;



To initiate the test, press ✓ (F4). The UNI-SIM will inflate the system until the protection valve is activated;



At the end of the test, the UNI-SIM will show the set-point of the protection valve (ie 331 mmHg)

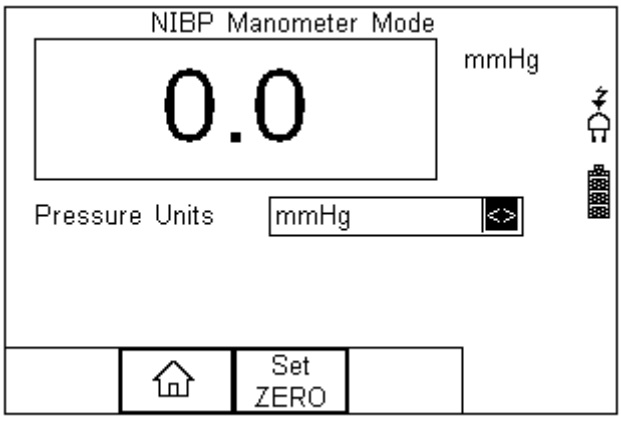
Press ✓ (F4) to repeat the test

Press ⌂ (F2) to return to start menu

5.5 NIBP Manometer Mode

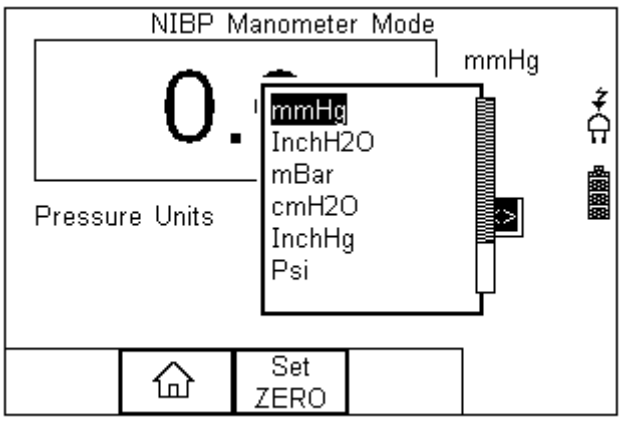
The UNI-SIM has a built-in manometer function which allows the user to measure the pressure in a number of engineering units;

Select the Manometer mode from the NIBP menu;



Ensure the manometer is set to zero by pressing the SET ZERO (F3) button) whilst the pressure connection at the UNI-SIM panel is open.

Select the engineering unit from the drop-down box using the left and right keys:



The manometer will automatically convert the pressure to the desired pressure unit.

Press (F2) to return to start menu

5.6 Set Zero

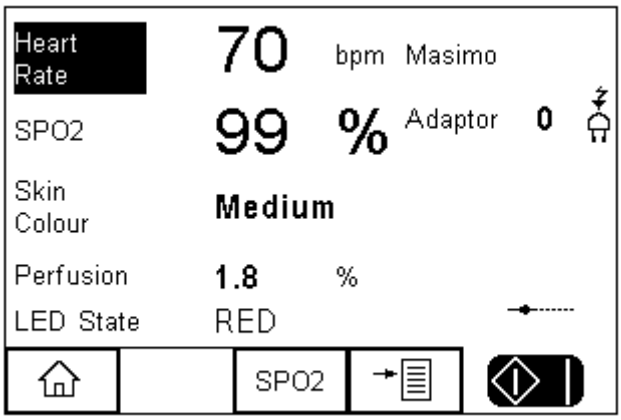
The Set Zero function is required to ensure the manometer is pressurised to the ambient pressure.

6 Manual Mode SPO2

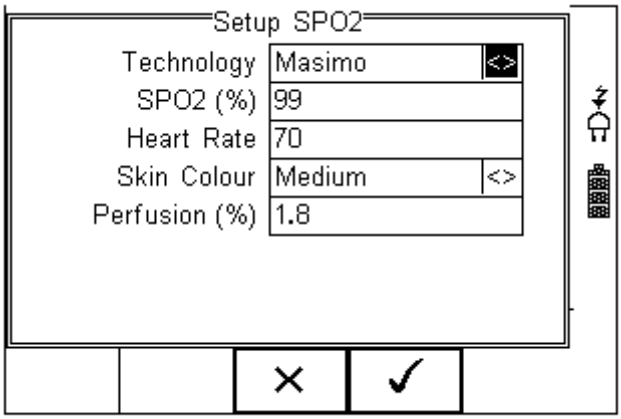
The Manual mode provides the user with the features of testing a specific individual test and or test condition for example to test a selection of:

- SPO2 value
- Heart rate
- Manufacturer R-curves
- Skin colour
- Perfusion
- Arrhythmia's (upgrade)
- Artefacts (upgrade)
- Chronometer function
- Checking of LED quality (both Red and InfraRed)

Press SPO2 (F2) from the start screen;

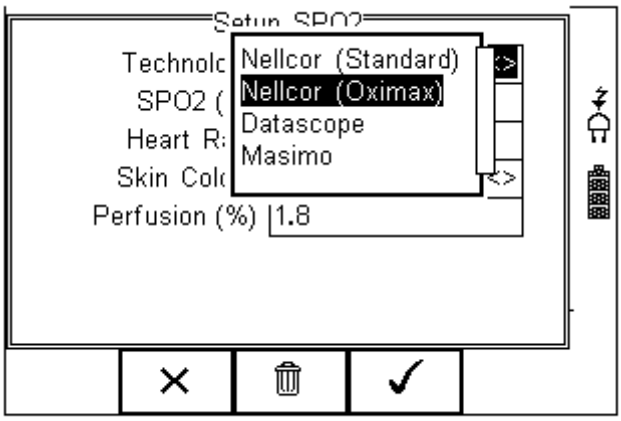


When SPO2 is selected, a number of options will be available;



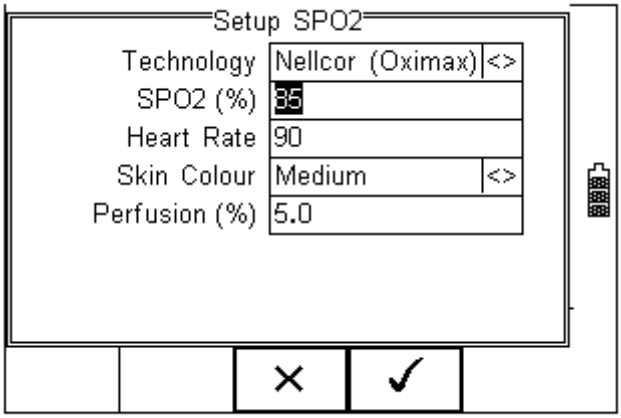
Navigate using the Up & Down Keys and change each setting by using the left key.

Technology; Select between the various R-curves;

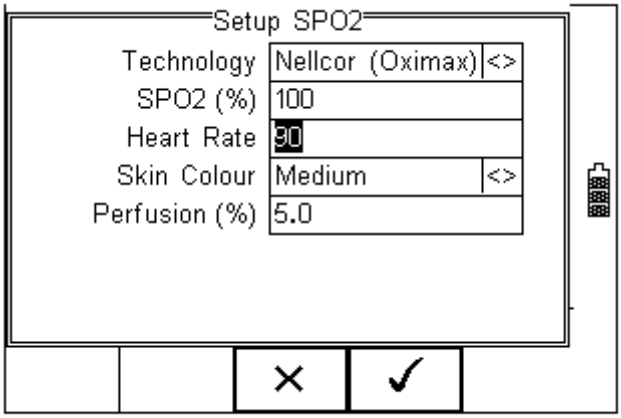


The list of available R-curve data is under constant development. Please monitor our website for new firmware releases. New firmware can be uploaded by the end-user and does not void the calibration of the device. Please go to: http://www.rigelmedical.com/downloads.asp

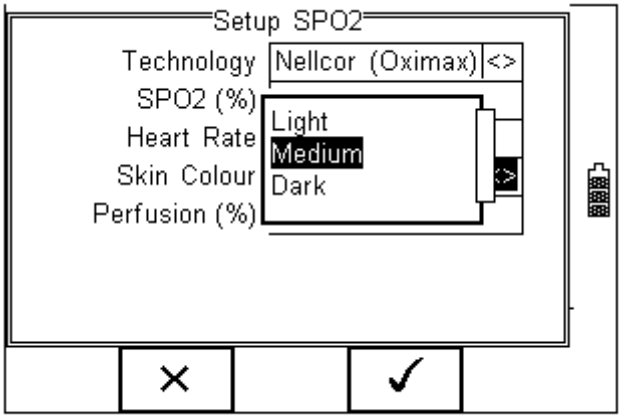
SPO2; Enter the required simulation value in %



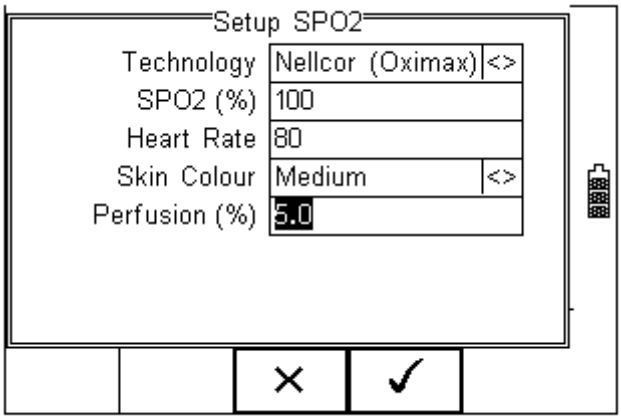
Heart Rate; Enter the required simulated heart rate;



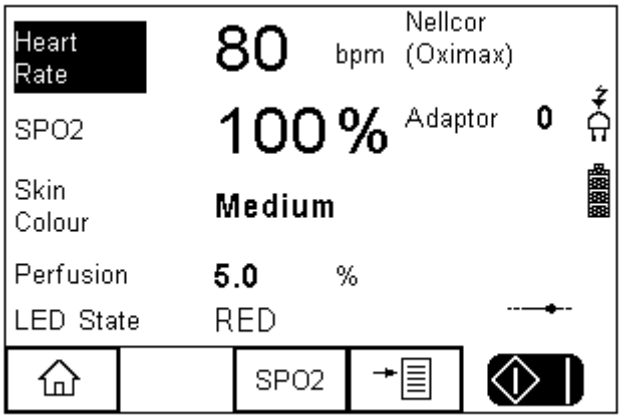
Skin Colour Select different levels of simulations of different skin colours.



Perfusion: Select the required signal strength to simulate different patient conditions ie infant, obese, average. Enter a value between 0 – 20% in steps of 0.1% where 5% is average perfusion.

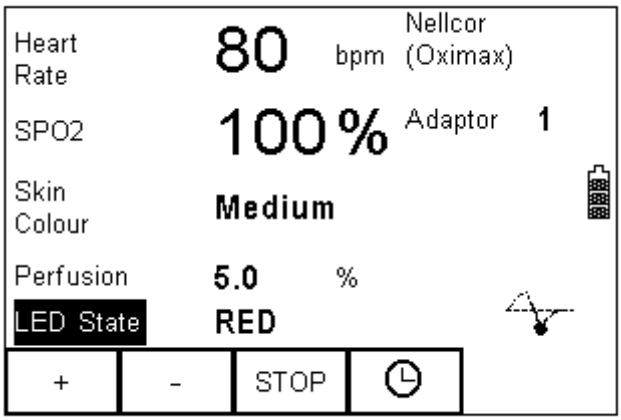


Once the selections are complete, select the ✓ (F4), to confirm the settings;



Press the Green Start key to start the simulation or press the key to return to the main summary screen.

When the simulation is in progress, a “pulse” symbol will be shown;



Whilst the simulation is being performed, the UNI-SIM can change settings. Use the arrow keys to scroll to the setting and use the “+” and “-“ keys to change the values.

Use the timer key to start the chronometer function which will record the time taken from one simulation setting to the next.

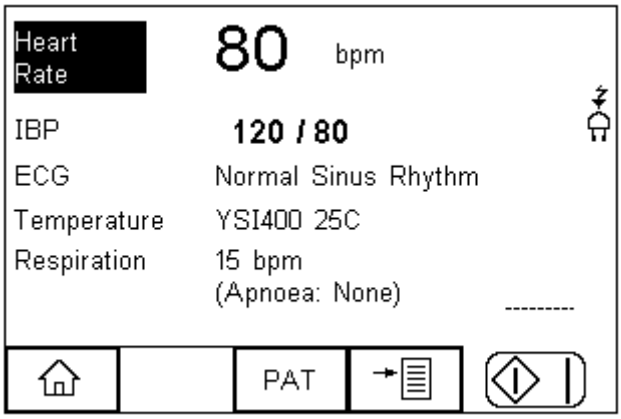
Note: The UNI-SIM simulates both Red and Infrared data through either of the Red or InfraRed LED’s at any given time. This allows the user to test the quality of individual probes and circuits. Tests have shown that worn probes might still provide a reading on the monitor though the accuracy or functionality is not guaranteed. By altering the simulation through the Red and Infrared circuits, one can detect anomalies between the two simulations (should be within 1%) which would indicate a potential problem with either one of the circuits.

7 Manual Mode Patient Simulator

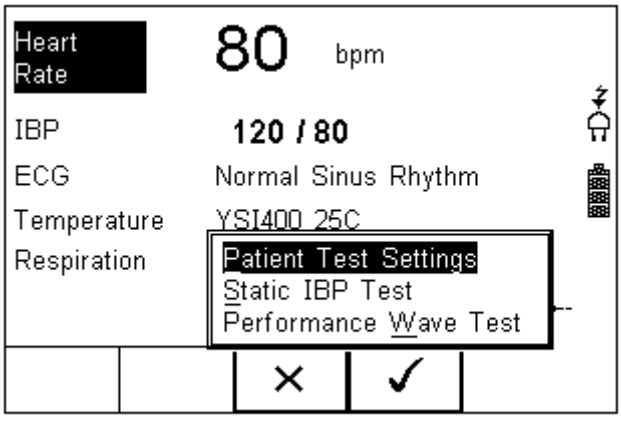
The Manual mode provides the user with the features of testing a specific individual test and or test condition for example to test a selection of:

- ECG wave forms
- Arrhythmia's
- Performance wave forms
- Respiration
- Temperature
- Invasive blood pressure

Press PAT (F1) from the start summary screen;



When PAT is selected, a number of options will be available;



- Patient Test Settings (see 7.1)
- Static IBP Test (See 7.2)
- Performance Wave Test (see 7.3)

7.1 Patient Test Settings

Select the Patient test Settings, to set the parameters for:

- Heart rate
- ECG waveforms, Arrhythmia's and amplitudes
- Invasive blood pressure settings
- Temperature simulation settings
- Respiration settings

The different options above are available across three individual screens accessible using the tab button (F2)

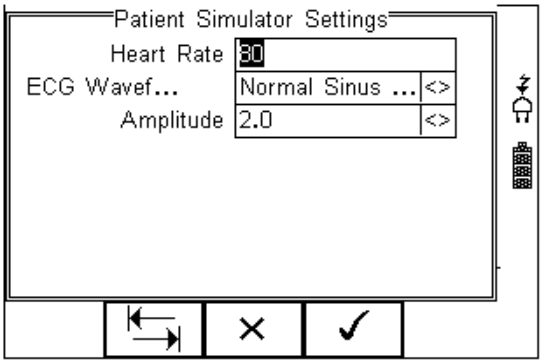


Figure 1 Patient Screen 1

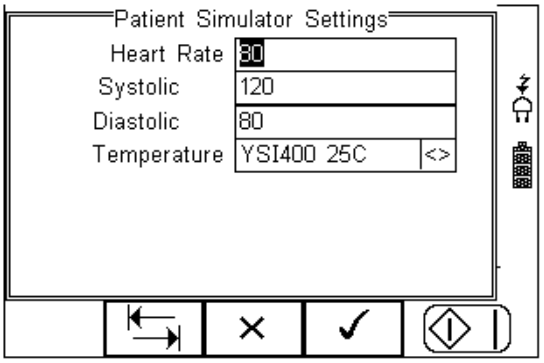


Figure 2 Patient Screen 2

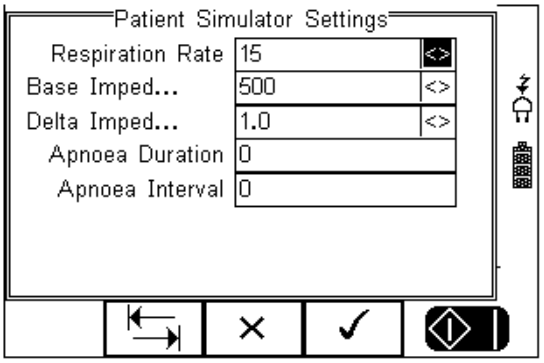
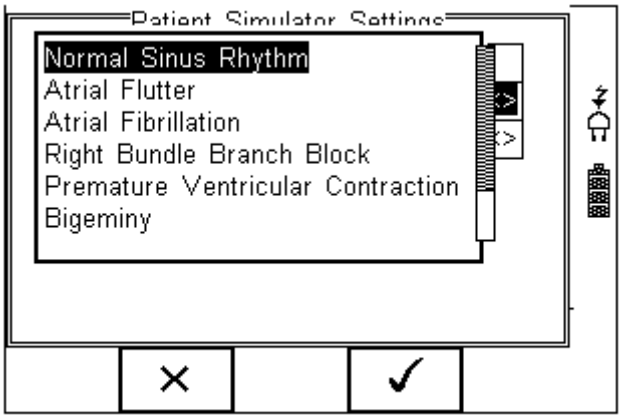


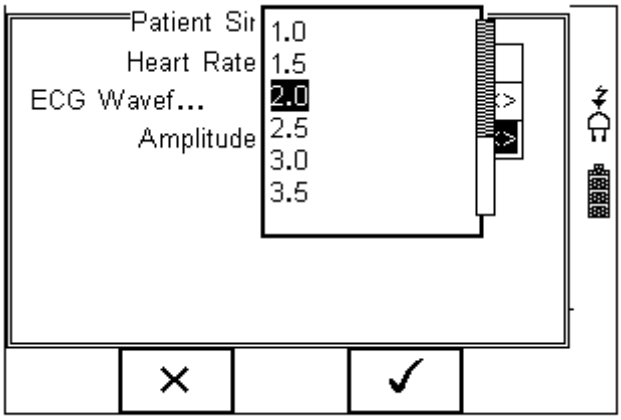
Figure 3 Patient Screen 3

7.1.1 Changing the ECG or Arrhythmia simulation

Referring to Patient Screen 1 (fig 1), manually enter the required heart rate.
The preferred ECG waveform or Arrhythmia and amplitude can be selected by selecting the dropdown box (right arrow key) and use the up and down keys to select;



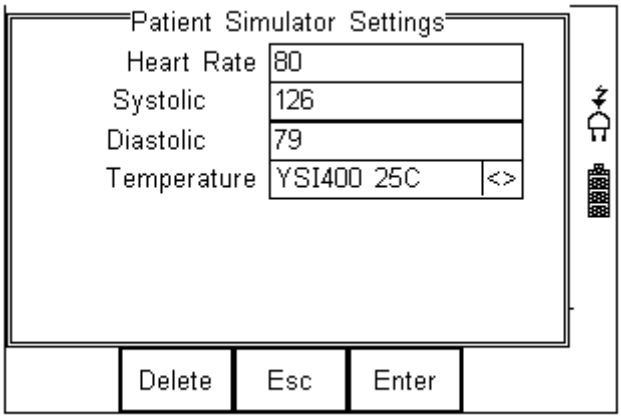
Select by pressing the ✓ key (F4) and confirm.
Repeat the same actions to change the signal amplitude;



Select by pressing the ✓ key (F4) and confirm again using the ✓ key (F4) or press the ⇤⇥ Key (F2) to make further changes.

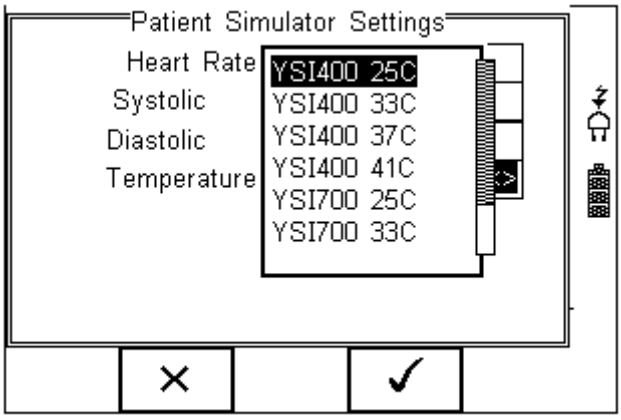
7.1.2 Changing the Invasive blood pressure settings

Referring to Patient Screen 2 (fig 2), manually enter the required heart rate, Systolic and Diastolic pressures and press ENTER to confirm;



7.1.3 Changing the Temperature settings

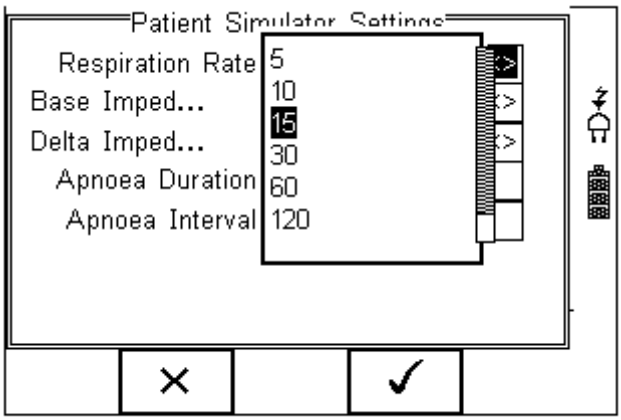
The preferred Temperature simulation (YSI 400 and 700) can be selected by selecting the dropdown box (right arrow key) and use the up and down keys to select;



Select by pressing the ✓ key (F4) and confirm again using the ✓ key (F4) or press the ⟷ Key (F2) to make further changes.

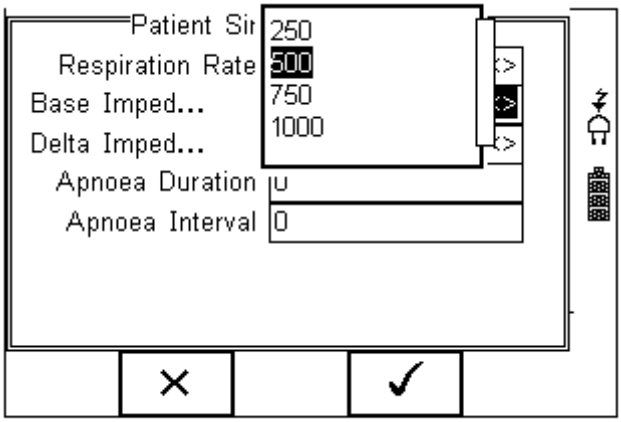
7.1.4 Changing the Respiration settings

Referring to Patient Screen 3 (fig 3), choose the respiration rate from the drop down box;

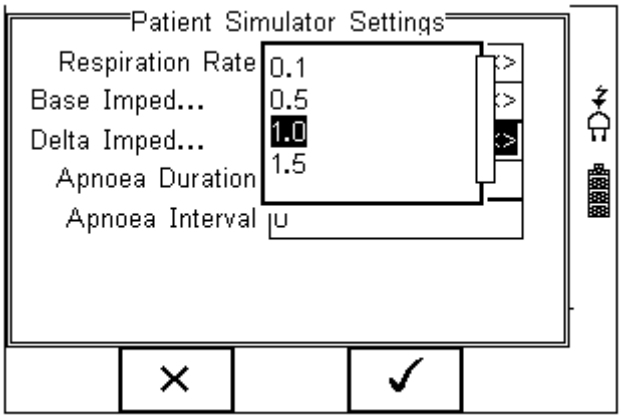


Select by pressing the ✓ key (F4).

Repeat the same for the Base Impedance and Delta Impedance;

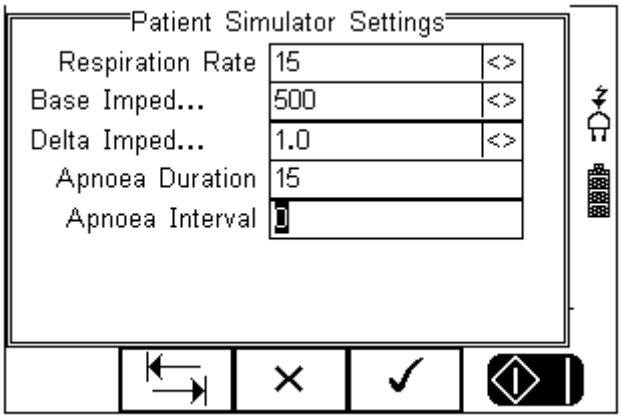


Select by pressing the ✓ key (F4)



Select by pressing the ✓ key (F4)

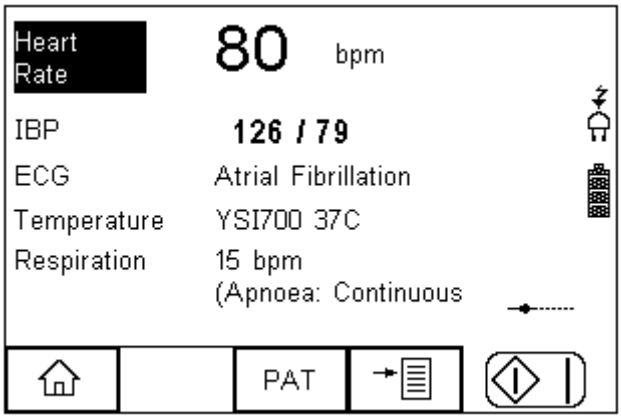
To simulate an Apnoea, enter the duration and interval (time between Apnoea)in seconds:



Note that an Apnoea Duration of "0" equals no Apnoea. A value of "0" for Apnoea Interval would result in a constant Apnoea if a value greater then "0" is entered for the Apnoea duration.

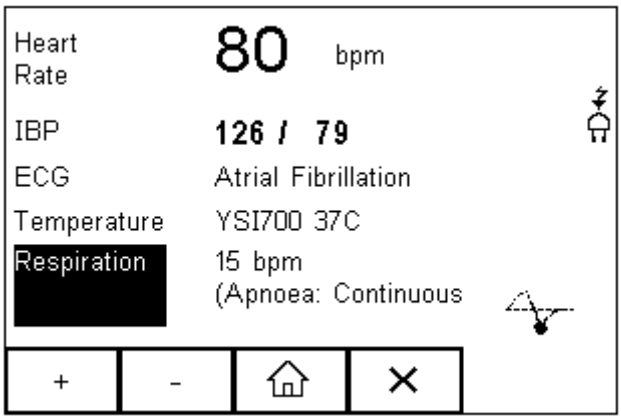
Confirm by pressing the ✓ key (F4) and confirm again using the ✓ key (F4) or press the ⟷ Key (F2) to make further changes.

The updated information is now available from the Patient Simulator Summary Screen below:



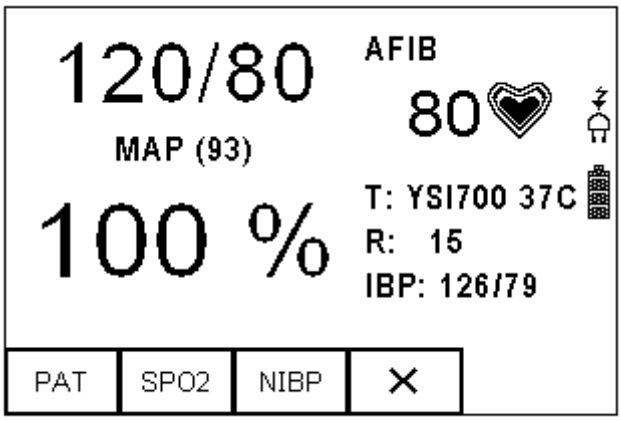
Press the Green Start key to start the simulation or press the ⌂ key to return to the main summary screen.

When the simulation is in progress, a “pulse” symbol will be shown;



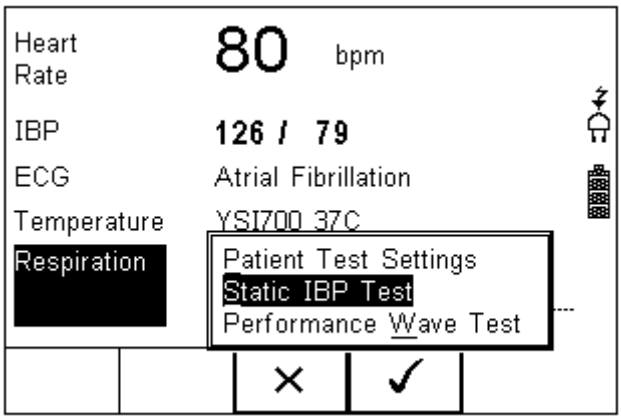
Whilst the simulation is being performed, the UNI-SIM can change settings. Use the arrow keys to scroll to the setting and use the “+” and “-“ keys to change the values.

Press the Green Start key to start the simulation or press the key to return to the main summary screen.

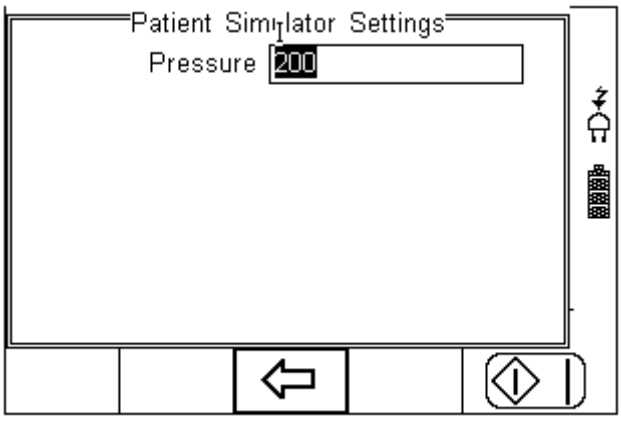


7.2 Static IBP Test

The Rigel UNI-SIM is able to simulate a static pressure using the invasive output. Select the Static IBP Test from the PAT menu, see below:



In the next screen, enter the required static pressure setting; The value entered is in mmHg and the UNI-SIM will simulate using an output of 5µV/V/mmHg.



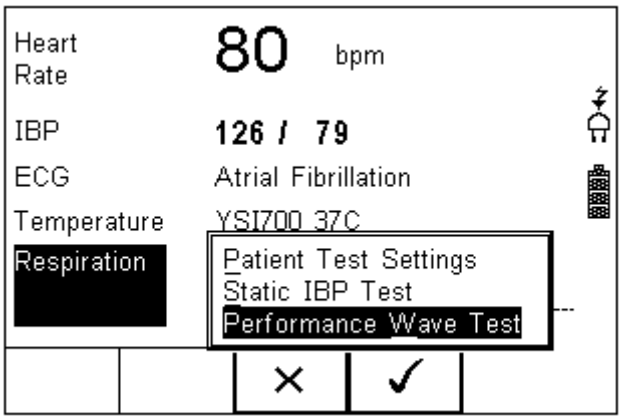
The simulation is continuously running whilst in this screen. When exiting this screen, the UNI-SIM will revert back to the systolic and diastolic settings, see 7.1.2)

Press the ⇦ key to return to the previous screen.

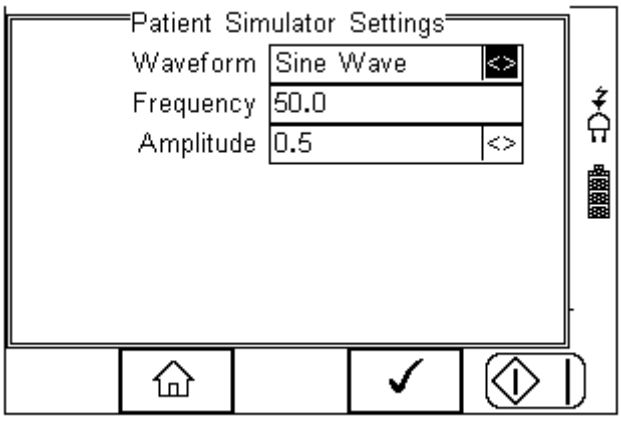
7.3 Performance Wave Test

The Rigel UNI-SIM is able to simulate a number of performance waveforms to calibrate the input circuit of ECG recorders and monitors.

Select the Performance Wave test from the PAT menu, see below:

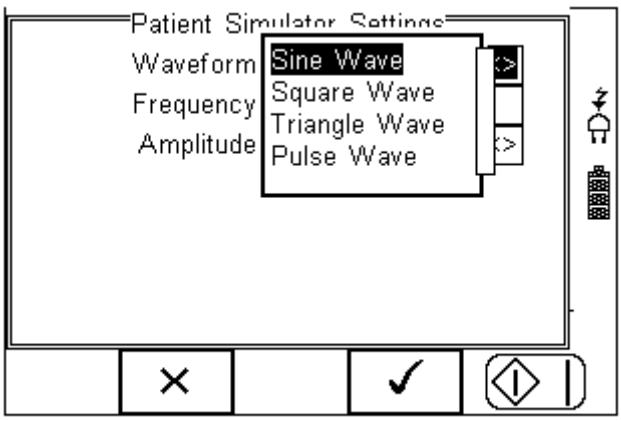


In the next screen, select the required wave form, frequency and amplitude settings:



The preferred wave form and amplitudes can be selected by selecting the dropdown box (right arrow key) and use the up and down keys to select. The frequency can be entered manually.

Note that the Pulse Wave has no frequency option, it is a fixed 20ms pulse every 4 seconds.



Confirm by pressing the ✓ key (F4). The simulation is only running whilst in this screen. When exiting this screen, the UNI-SIM will revert back to the ECG simulation settings, see 7.1.1

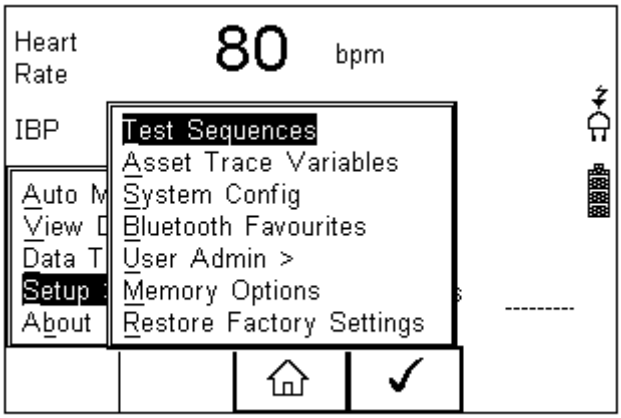
Press the ✕ key (F2) to return to the previous screen

8 Setting-up your tester

The Rigel UNI-SIM is designed to allow the user to customise the device to allow default setting in order to speed up the testing such as, default lists of manufacturers, model numbers, user test protocols, automatic printing following test, fault menu's and so on.

All custom facilities can be found under the SETUP menu. Simply press the [F4] from the home screen and select Setup from the menu.

Hint: The underlined character acts as a short key to allow swift navigation through the menu structure.



Options available

Test Sequences	Modify or create test sequences (see 8.1)
Asset Trace Variables	Generate default list of variables (see 8.2)
Systems Config	Configure default test options (see 8.3)
Bluetooth Favourites	Setup your Bluetooth devices (see 8.4)
User admin	Setup users and preferences (see 8.5)
Memory Options	Manage the tester's memory (see 8.6)
Restore Factory Settings	Defaults the tester to factory settings (see 8.7)

8.1 Test Sequences

The Rigel UNI-SIM can be set-up to create new test sequences to meet monitor specific requirements or to modify existing test sequences to meet personal preference.

Preset test sequences cannot be changed by the user, however alterations are possible by producing a copy of the default test sequence setting.

The total number of possible preset test sequences is 50 including 12 default test sequences.

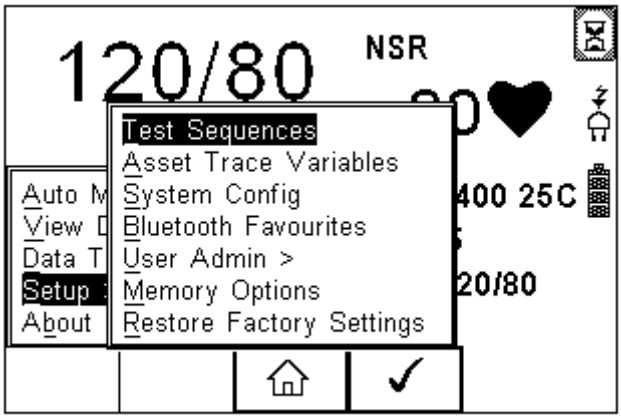
8.1.1 Create a new Test Sequence

The available options for inseting tests are provide in table T1 below:

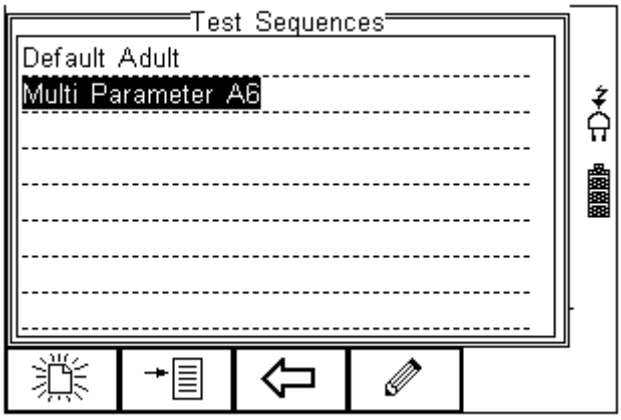
Pos	Title	Description	Ref.
1	NIBP Simulation Settings	Select the type of O'curve, systolic and diastolic simulation values, heart rate and pulse volume.	NIBP Test Settings 5.1
2	SPO2 Simulation Settings	Select the type of R'curve, SPO2 simulation values, heart rate, red/infra red simulation, perfusion and skin colour.	6
3	Patient Simulation Settings	Select the type of ECG waveform, Arrhythmia, IBP, temperature and respiration settings.	7.1
4	Start Simulations	This must be inserted in order to start the simulation part of the UNI-SIM and defines the duration of the simulations. Without this instruction, none of the above settings will be simulated. If more then one setting for individual simulations is required ie 2 x NIBP, this instruction must be inserted twice at the end of each new setting.	NA
5	NIBP Leak Test	Perform a system of cuff leak test by setting the set value and time duration.	5.2
6	NIBP Pop-off test	Perform a system overpressure release test recording the sudden pressure release.	5.4
7	NIBP Static Pressure test	Perform a static pressure test by setting the required value. Multiple static pressure tests can be inserted, starting with the lowest value and going up.	5.3
9	NIBP Stop Static Pressure test	This must be inserted in order to stop the static pressure tests and release the pressure from the system prior to starting the simulations. Without this instruction, none of the simulations will start.	NA
10	IBP Static Test	Perform a static IBP test by setting the required value.	7.2
11	Performance Wave test	Simulate a performance waveform	7.3
12	Custom Test	Insert cusom tests or instructions by using free text fields. The user must confirm, or enter a value in each field. Insert as many fields as required at the appropiate position in the test sequence.	8.1.12

Table 1. Available tests for insertion in auto sequence

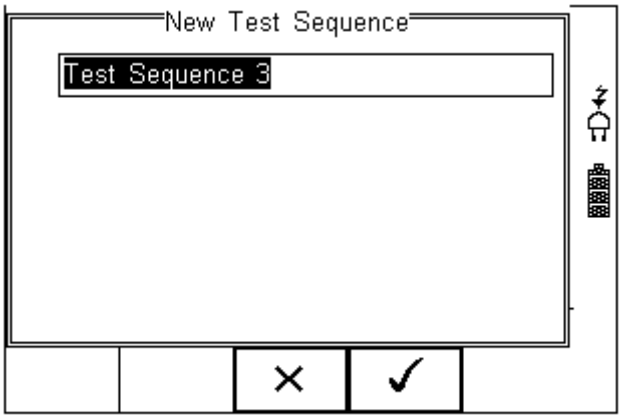
To create a new Test Sequence, enter the Menu button (F4) from the home screen, select Setup followed by Test Sequences from the menu.



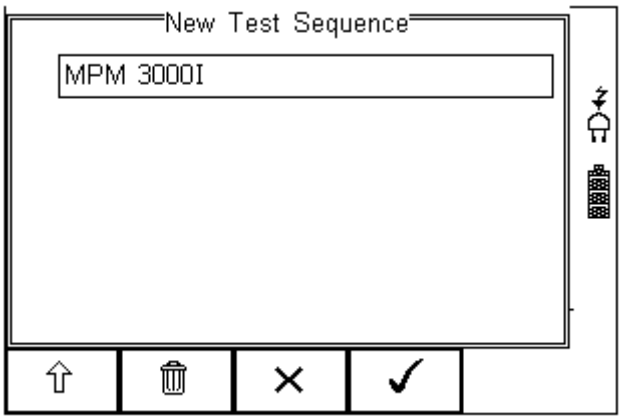
The following screen displays the list of default and customised tests available. Copied Test Sequences will appear in the list with an *pre-fix.



From this menu, the user is able to create a new Test Sequence by pressing the button (F1).



Use the keyboard to activate the text box. When activated, function keys F1 ⇧ and F2 🗑 appear automatically. In this instance ‘Customer test 1’ has been created as Test Name.



To change to upper or lower case or use language specific charaters, press the ⇧ button (F1) and select the required entry.

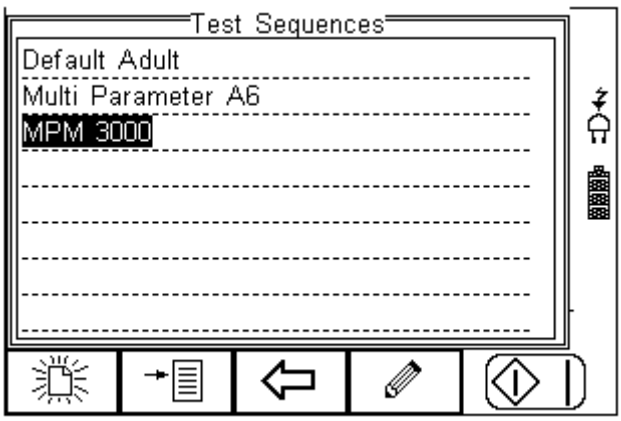
To Delete a character, press the 🗑 button (F2)

To return to the previous menu without changes, press the ✕ button (F3)

To confirm the entry, press the ⏎ button (F4)

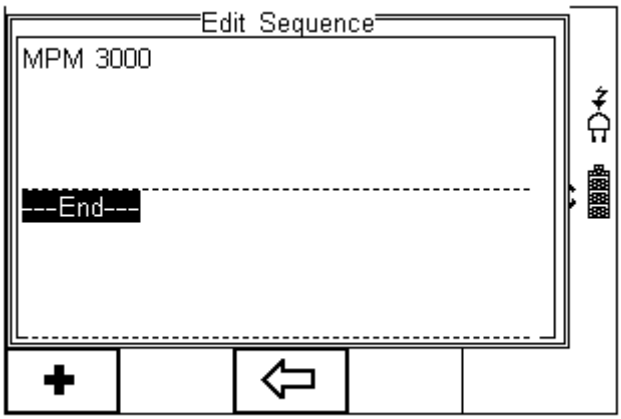
Next step is to save the name of the newly create Test Name, by pressing the OK button (F4). Pressing the ✕ key (F3) would return to the Test Sequence menu without changes.

The newly created Test Name now appears in the Test Sequence menu and can be modified to include the required individual tests. Press the ✎ button (F4) to open the sequence for editing.



Once the Test Sequence has been opened, individual tests can be inserted by highlighting the place where a new test needs inserting using the up and down keys.

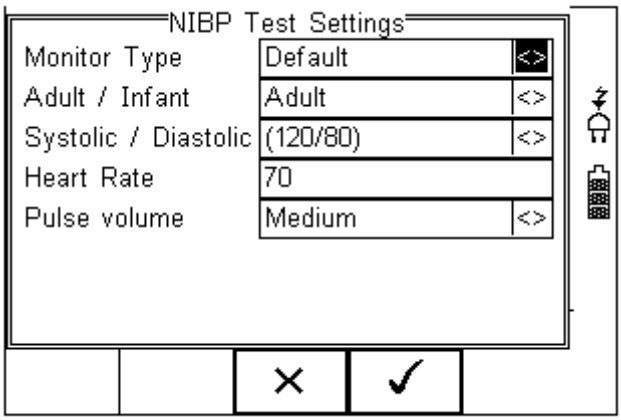
To modify a test sequence, please refer to 8.1.15



To insert a test, press the ✚ key (F1), **Note; Tests will be inserted before the highlighted position not after.**

8.1.2 Insert NIBP test settings

Use the NIBP Test Settings to setup a selection of Dynamic Pressure simulations.



Navigate using the Up & Down Keys and change each setting by using the left key.

Refer to the instructions in 5.1 for more options available.

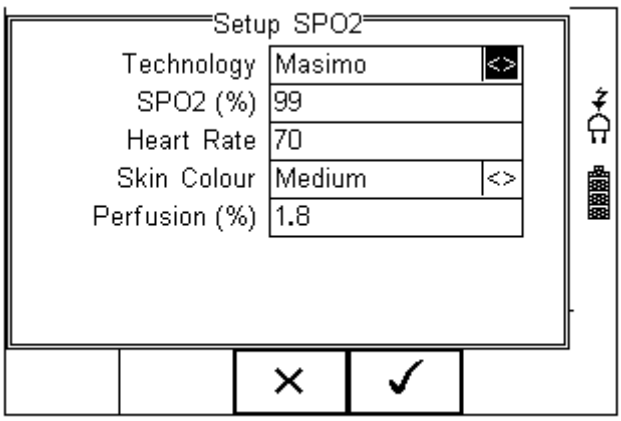
Confirm and insert by pressing the ✓ key (F4).

8.1.3 Insert SPO2 test settings

Use the SPO2 test settings to set the required parameters for SPO2 simulation;

- SPO2 value
- Heart rate
- Manufacturer R-curves
- Skin colour
- Perfusion
- Arrhythmia's (upgrade)
- Artefacts (upgrade)
- Checking of LED quality (both Red and InfraRed)

Insert the SPO2 Test Settings from the drop down list and press the key to edit the test settings.



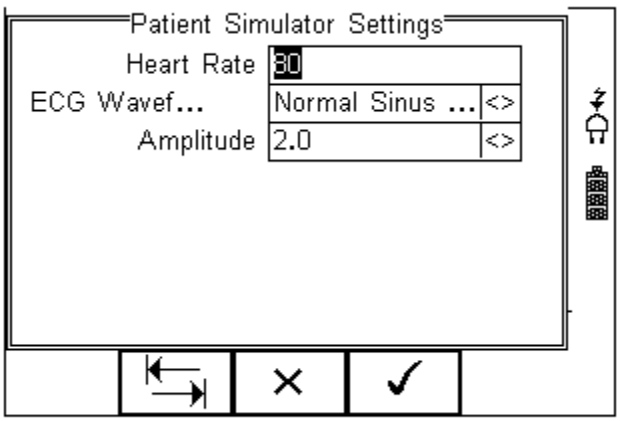
Navigate using the Up & Down Keys and change each setting by using the left key. Refer to the instructions in 5.16 for more options available.

Confirm and insert by pressing the ✓ key (F4).

8.1.4 Insert Patient Simulator settings

Select the Patient test Settings, to set the parameters for:

- Heart rate
- ECG waveforms, Arrhythmia's and amplitudes
- Invasive blood pressure settings
- Temperature simulation settings
- Respiration settings



The different options above are available across three individual screens accessible using the tab ⟷ button (F2)

Navigate using the Up & Down Keys and change each setting by using the left key.

Refer to the instructions in 5.17.1 for more options available.

Confirm and insert by pressing the ✓ key (F4).

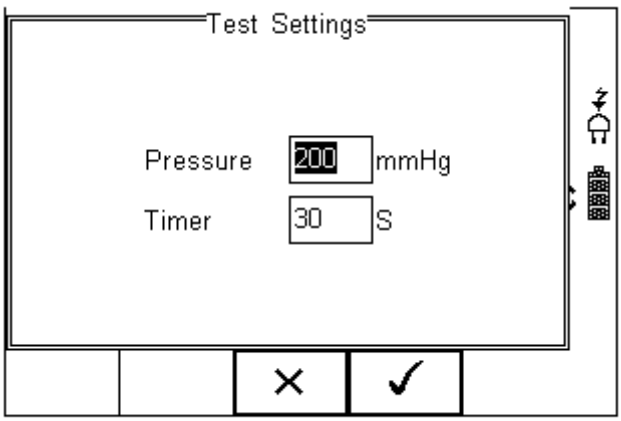
8.1.5 Start Simulations

In order to start the simulations on the UNI-SIM, “Start All Tests” instruction must be inserted and defines the duration of the simulations. Without this instruction, none of the simulations will be simulated. If more then one setting for individual simulations is required ie 2 x NIBP, this instruction must be inserted after each simulation setting.

8.1.6 NIBP Leak Test

Perform a system or cuff leak test by setting the set value and time duration.

Insert the NIBP Leak Test Settings from the drop down list and press the key to edit the test settings.



Navigate using the Up & Down Keys and enter the required values.
Refer to the instructions in 5.15.2 for further instructions on the options available.

Confirm and insert by pressing the ✓ key (F4).

8.1.7 NIBP Pop-off test

Perform a system overpressure release test recording the sudden pressure release.

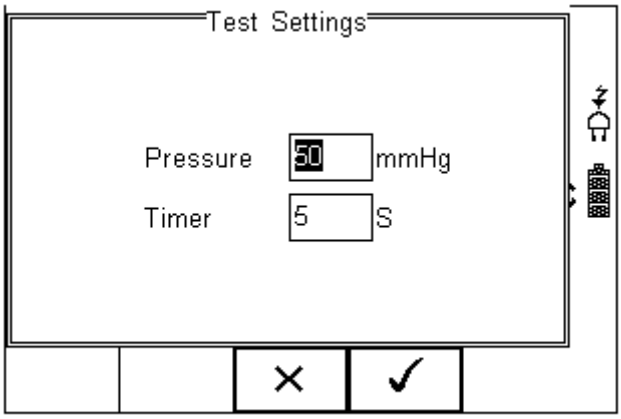
Insert the NIBP Pop-off test from the drop down list. Note that there are no settings to change.

Refer to the instructions in 5.45.1 for further instructions on the options available.

8.1.8 NIBP Static Pressure test

Perform a static pressure test by setting the required value. Multiple static pressure tests can be inserted, starting with the lowest value and going up. See 8.1.9 for instructions on ending the static pressure test.

Insert the NIBP Static Pressure Test Settings from the drop down list and press the key to edit the test settings.



Navigate using the Up & Down Keys and enter the required values.
Refer to the instructions in 5.15.3 for further instructions on the options available.

Confirm and insert by pressing the ✓ key (F4).

8.1.9 NIBP Stop Static Pressure test

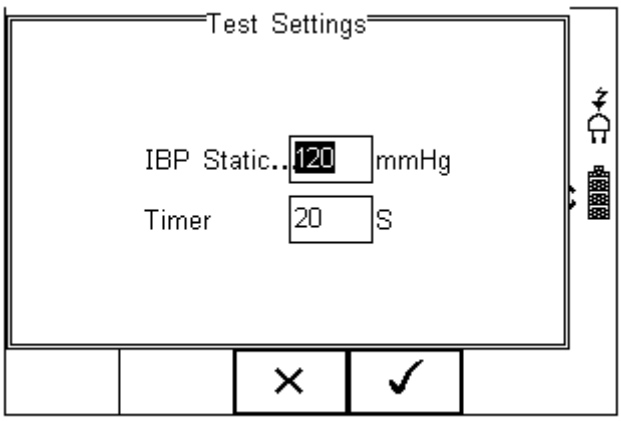
This must be inserted in order to stop the static pressure tests and release the pressure from the system prior to starting the simulations. Without this instruction, none of the simulations will start.

Insert the NIBP Stop Static Pressure Test from the drop down list. Note that there are no settings to change.

8.1.10 IBP Static Test

Perform a static IBP test by setting the required value.

Insert the IBP Static Test Settings from the drop down list and press the key to edit the test settings.



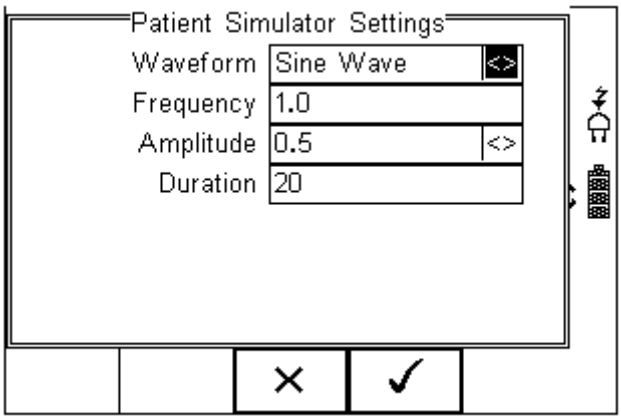
Navigate using the Up & Down Keys and enter the required values.
Refer to the instructions in 5.17.2 for further instructions on the options available.

Confirm and insert by pressing the ✓ key (F4).

8.1.11 Performance Wave test

Simulate a performance waveform

Insert the Performance Wave Test Settings from the drop down list and press the key to edit the test settings.



Navigate using the Up & Down Keys and enter the required values.
Refer to the instructions in 5.17.3 for further instructions on the options available.

Confirm and insert by pressing the ✓ key (F4).

8.1.12 User definable tests

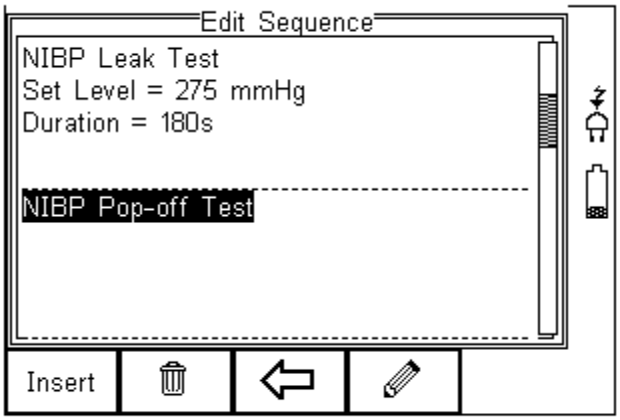
Custom tests or Instructions are intended to allow the user to capture additional information either prior to or after the main simulation and performance tests. Such information could indicate the condition such as Labels, software version, certain damage or upgrades. To create customised inspections, use the insert Custom Test function using the instructions below and set the engineering units to blank.

The input is text only and no simulations or measurements are performed by the Rigel UNI-SIM during these tests. The maximum number of **characters** in the test description or instruction is 255.

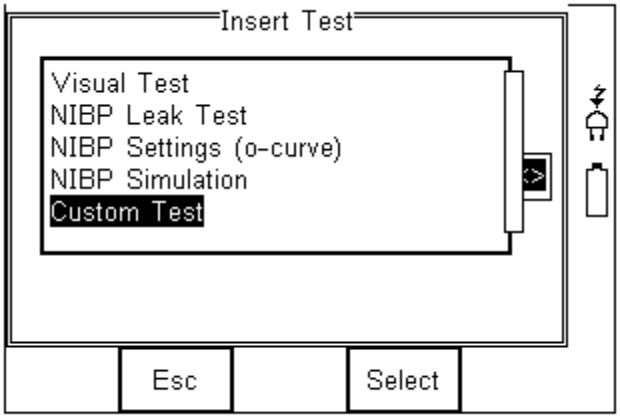
Hint: Create a unique range of visual tests or instructions by creating a new test sequence (see 8.1.1) and select Custom Test as the nature of the test. This will create a unique test sequence.

To insert a Custom Test, highlight the place where a new test needs inserting using the up and down keys and press the Insert button (F1) from the menu below.

Note; Tests will be inserted before the highlighted position not after.

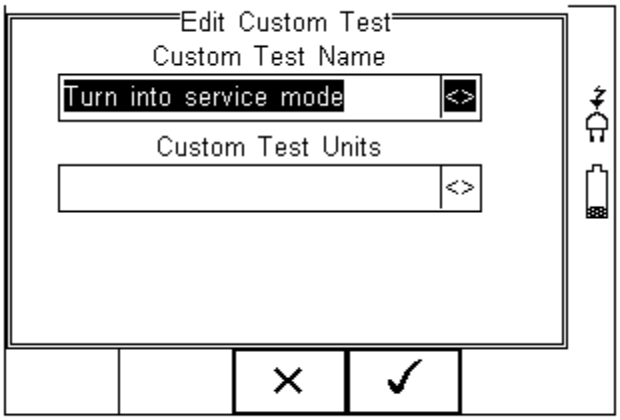


Once the Insert button (F1) has been pressed, a drop down box will appear with all available tests and inspection available. Activate the drop down box using the left key and select the Custom Test option.

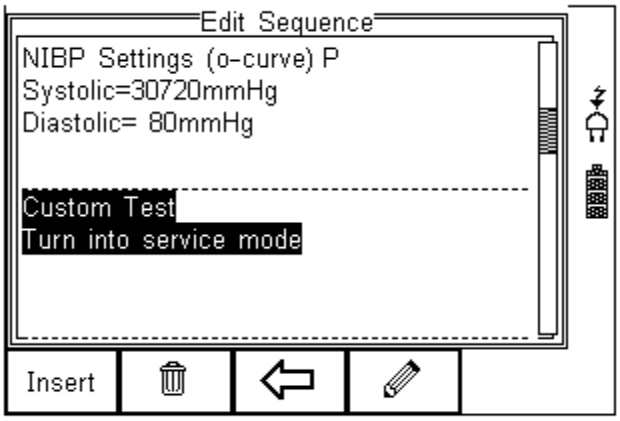


Confirm using the ✓ button (F4). The following menu will define the nature of the test (eg test Instruction prior to leak test)

Use the drop down box to choose a preset instruction and engineering unit or simply type in the boxes provided. Newly entered data will be added to the drop down box on a first come first serve basis.

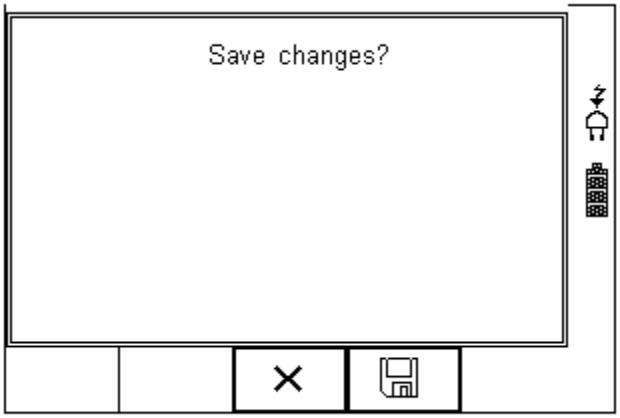


To insert the new Custom Test, press the ✓ button (F4) or exit using the ✕ button (F3) and return to the previous screen without changes being made.



Further tests can be inserted or deleted by following the steps described herein.

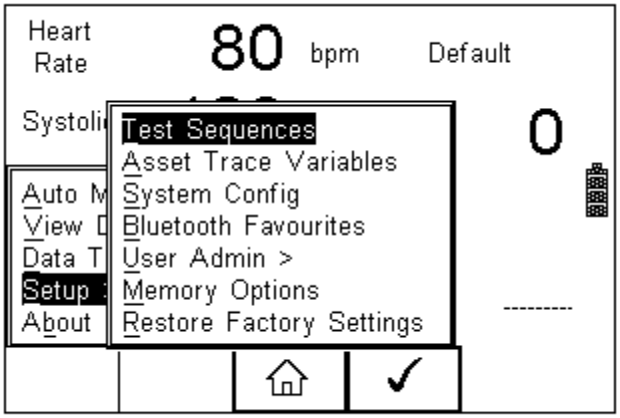
To exit and save the changes for future press the ⇦ button followed by pressing the 🖫 button. If the Escape button (F3) is pressed, the Rigel UNI-SIM will return to the previous meny without changes being made.



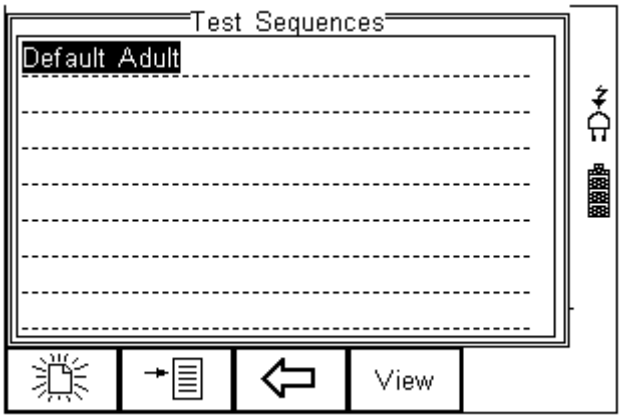
8.1.13 View, Delete or Copy an existing Test Routine.

Preset test sequences cannot be deleted or changed by the user however, alterations are possible by producing a copy of the default test sequence.

To enter the Test Sequences menu, click on , followed by Setup. Select the Test Sequences from the list and press (F4).

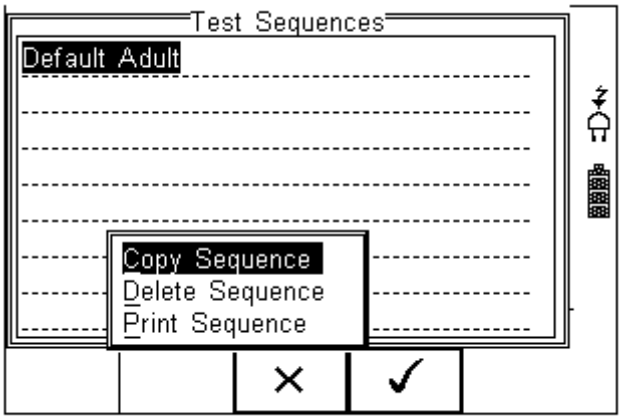


The following overview is provided and shows the list of default and customised test sequences availble. Copied Test Sequences will appear in the list with an *pre-fix.



From this menu, the user is able to View a test sequence by pressing the View button (F4). Default test settings cannot be altered at any stage.

To Copy, Delete or Print an existing or default test sequence, use the Up & Down arrow keys to highlight the test sequence and press the button (F2).



Use the Up & Down Arrow keys to select the required action and press the ✓ (F4) to confirm. Press Escape (F3) to cancel and return to previous screen.

Copied Test Sequences will appear in the list with an *pre-fix. All Copied test Sequences can be edited. See 8.1.14 for more on editing test sequences.

Print Test Sequence will provide an overview of the Test Sequence on the Favourite Bluetooth Printer. See 8.4 for help on setting up Bluetooth devices.

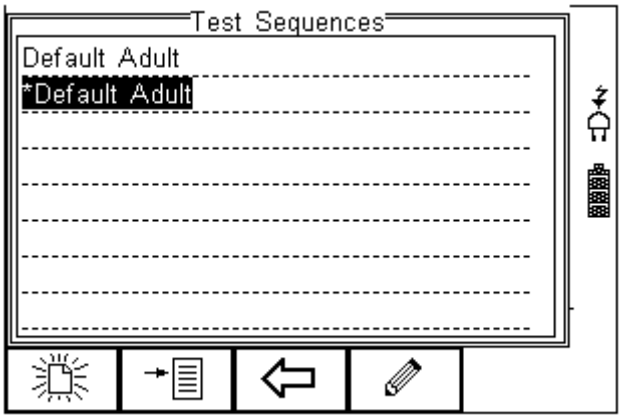
Delete Sequence will remove the highlighted test sequence from the memory of the Rigel UNI-SIM.

Note: Default Test Sequences cannot be Deleted.

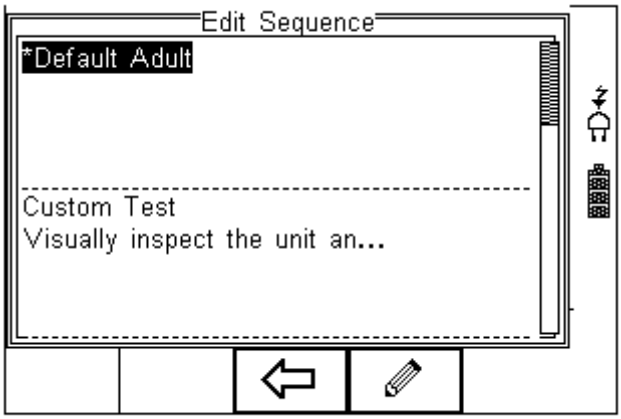
8.1.14 Modifying (Edit) Existing Test Sequences

Preset test sequences cannot be modified by the user, however alterations are possible by producing a copy of the default test setting (see 8.1.13).

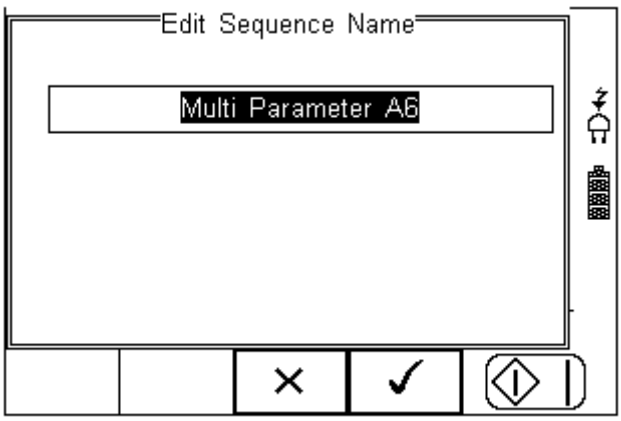
Non-default Test Sequences can be modified from the Test Sequences menu. When non-default Test Sequences are highlighted, the (F4) will appear in the menu screen.



Pessing the button (F4) will open the Test Sequence for Editing as shown below;



To change the Name and or Class of the Test Sequence, press the Button (F4) and enter the Name and or Class required.

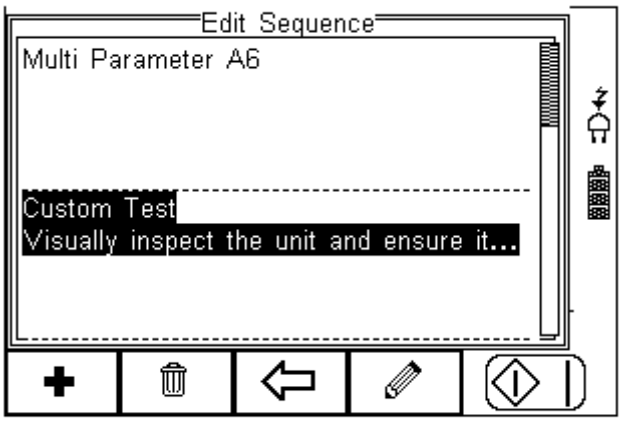


To change to upper or lower case or use language specific characters, press the ⇧ button (F1) and select the required entry.

To Delete a character, press the 🗑 button (F2)

To return to the previous menu without changes, press the ✕ button (F3)

Confirm by pressing the ✓ key (F4) or cancel using the ✕ button (F4).

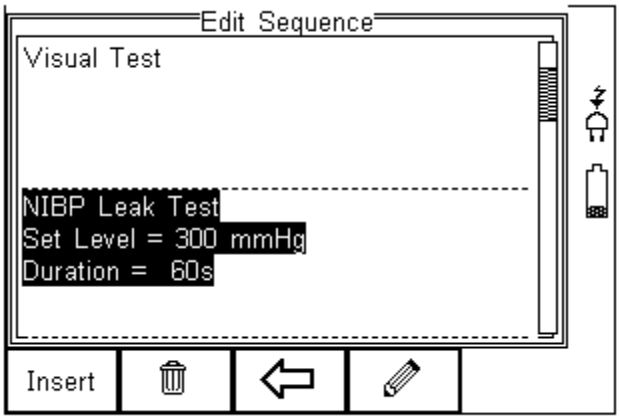


To Insert a new test, highlight the test using the Up & Down arrow keys and press the Insert button (F1)

To Delete an individual test, highlight the test using the Up & Down arrow keys and press the 🗑 button (F2)

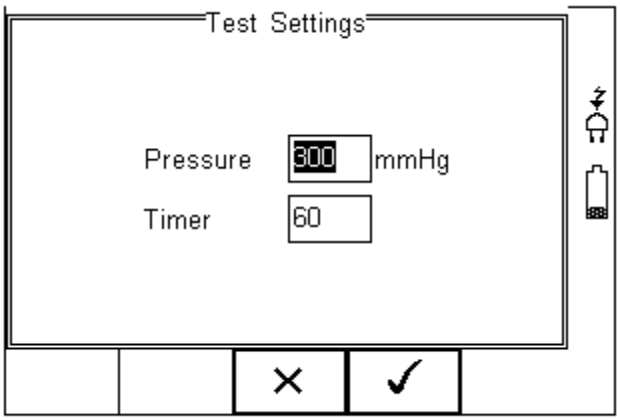
To go back to the previous menu, highlight the test using the Up & Down arrow keys and press the ✕ button (F3)

To modify an individual test, highlight the test using the Up & Down arrow keys and press the Button (F4)

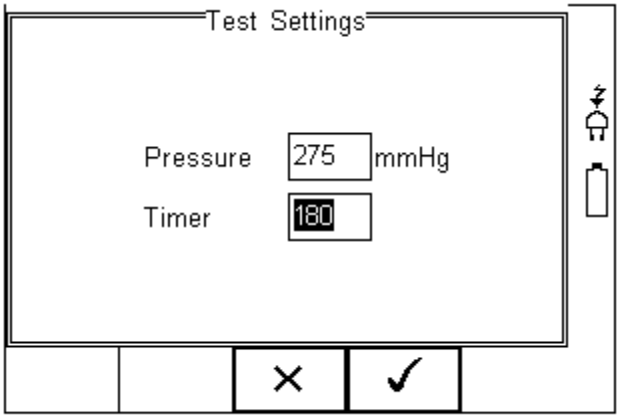


8.1.15 Edit individual Test

Press the button (F4) as shown above. The Leak Test sub menu will allow you to alter the settings for; Test duration and Pressure set point.



Highlight the required field using the up and down keys. To change the content use the keypad to enter the correct data. To Delete the field content, press the button as shown below.



When the right settings have been achieved, press the ✓ button (F4) to save the changes or press ✕ (F3) to return to the previous menu without changes.

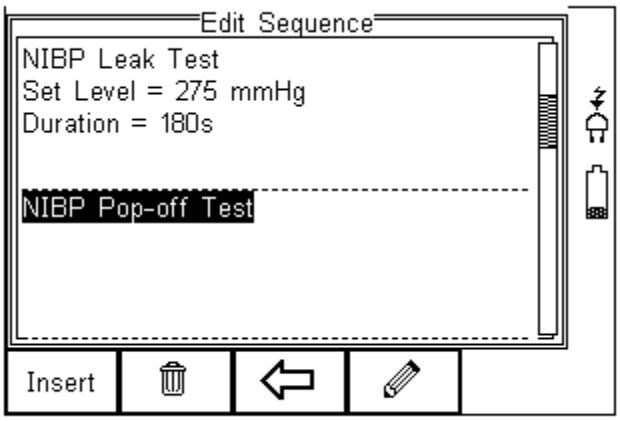
Repeat this action for every test that requires editing. Once all the requires tests are programmed, press ✕ (F3) to exit.

8.1.16 Insert an individual test

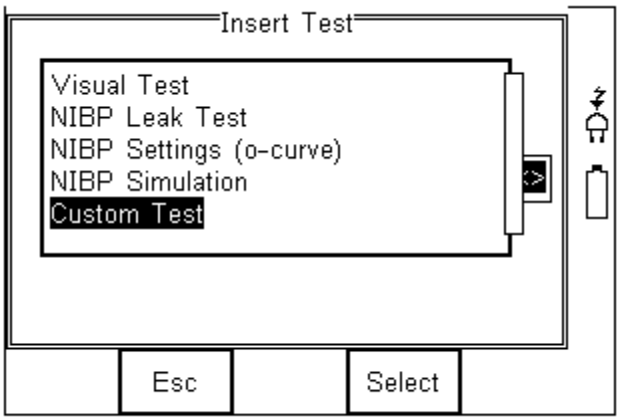
To insert an individual test we use the up and down keys to highlight the position where a new test needs inserting and press the Insert button (F1) from the menu below.

Note; Tests will be inserted before the highlighted position not after.

To modify a test sequence, please refer to 8.1.15

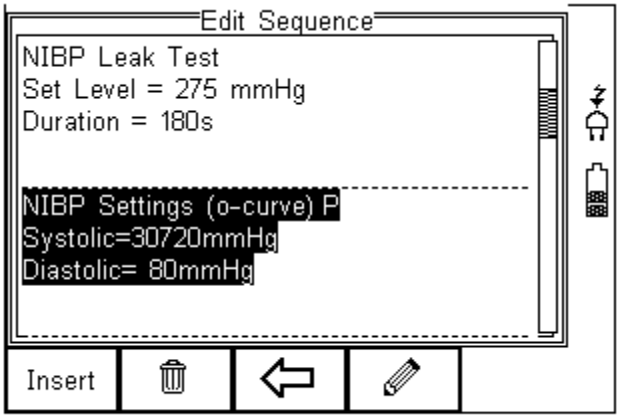


Once the Insert button (F1) has been pressed, a drop down box will appear with all available tests. Activate the drop down box using the left key and or scroll through the available tests using the up and down keys.



Once the desired test has been highlighted, confirm using the OK button (F4) and finally confirm to insert into the test Sequence. Pressing the ✕ button (F3) will return to the previous screen without changes being made.

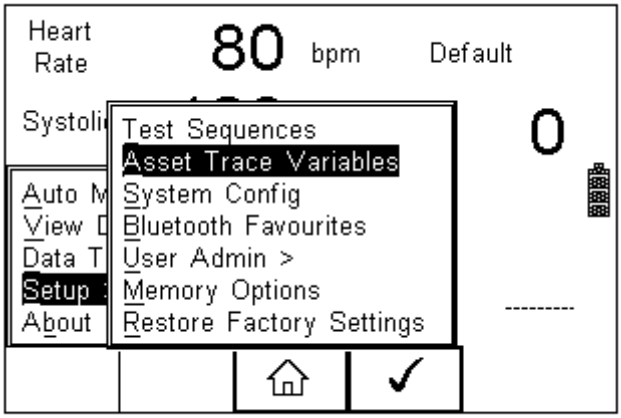
The individual test has now been inserted and can be edited as described in 3.1.4



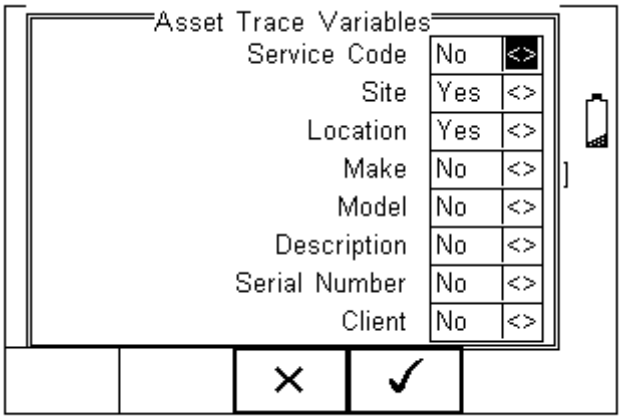
Further tests can be inserted or deleted by following the steps described herein.

8.2 Asset Trace Variables

The Asset Trace Variables allow the user to include valuable data to the test results to enhance the traceability and to provide increased search criteria when using database software. Asset trace variables may consist of a maximum of 25 characters and can be selected prior to each test when using the Rigel UNI-SIM in automatic mode.



The following variables can be added to the test results:



The default settings on the Rigel UNI-SIM include the Site and Location variables. Both are activated. The drop down box is set to [Yes].

To activate or de-activate each variable, use the up and down keys to select the variable and the left and right keys to select yes or no.

Once a variable has been activated, the user is given the ability to enter Trace Variables prior to a safety test by selecting from or adding to the list of default items. Each variable entered during the automatic test will automatically be added to the list for future use.

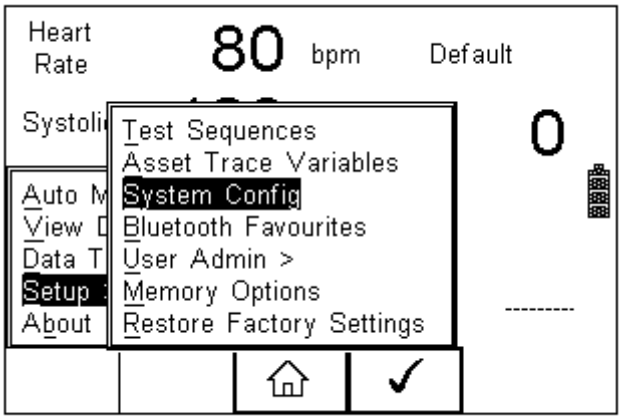
Trace Variables that are de-activated (set to NO) will not appear during the automatic tests.

Note that a maximum of 40 individual entries are available for each Trace Variable. Additional entries will overwrite on a first in first out basis.

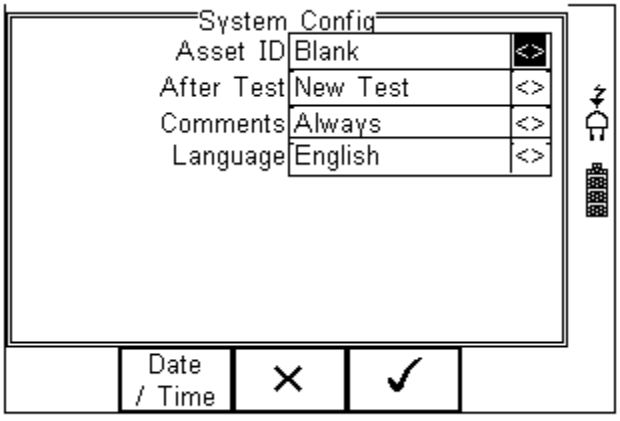
8.3 System Config

This feature can setup the Rigel UNI-SIM to automatically perform certain features during or after a test as well as allowing the user to set Time and Date preference.

To select System Config, press the button (F4) followed by Setup in the menu and System Config from the list as shown below;



The System Config menu is displayed below;



The System Config menu provides the following features:

8.3.1 Asset ID

Provides automatic Asset ID configuration. Use the Left & Right Keys to select between

- Increment - Automatically increments the next Asset ID's least significant number by 1
- Blank – Will leave the next Asset ID field blank
- Repeat Last - Will copy the previous Asset ID into the next Asset ID field

8.3.2 After Test

Provides automatic action after a test is completed. Use the left and right keys to select from the following

- New Test – Automatically brings up the next test screen.
- Download – Automatically down loads the test results to the PC (see 11.1)
- Print Label – Automatically prints the test results or label to a printer (see Appendix D)
- Options Menu – Provides a menu to allow further choices after a test. (see 9.3)

8.3.3 Comments

Provides the ability to enter further comments after successful or failed tests. Use the left and right keys to select from the following

- Always – Comment field is displayed after each passed or failed test.
- On Pass – Comment field is displayed after a passed test only.
- On Failure – Comment field is displayed after failed test only
- Never – Comment field is not displayed.

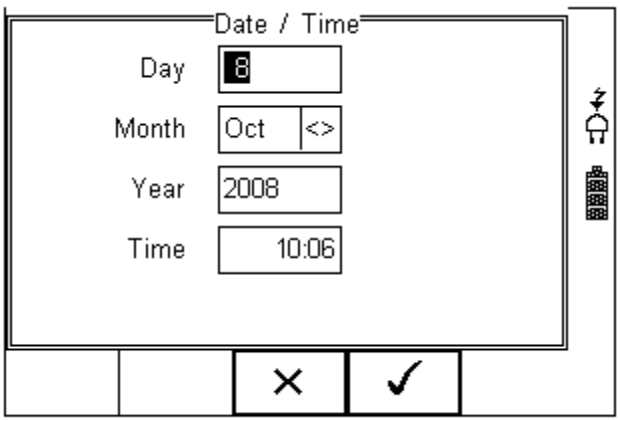
8.3.4 Language

Provides the ability to change the default language in the Rigel UNI-SIM. A number of languages are available and will be updated which ach firmware revision. Use the up, down, left and right keys to select from the available languages. Additional languages (firmware upgrades) can be downloaded from **www.rigelmedical.com** or contact your local Rigel sales office (UK ; +44 (0) 191 5878701)

8.3.5 Date / Time

Allows the user to set the current date / time and preferred formats.

Press the Date / Time button (F2). The following menu will be displayed;



Day	Enter current day
Month	Use the up, down, left and right keys to select the current month
Year	Enter current year
Time	Enter current time. Use the ':' (F1) to separate hours from minutes to ensure the correct time is entered and saved.

Confirm the settings by pressing the ✓ button (F4)

Ones all System Configurations have been completed, press the ✓ button (F4). Changes are saved automatically.

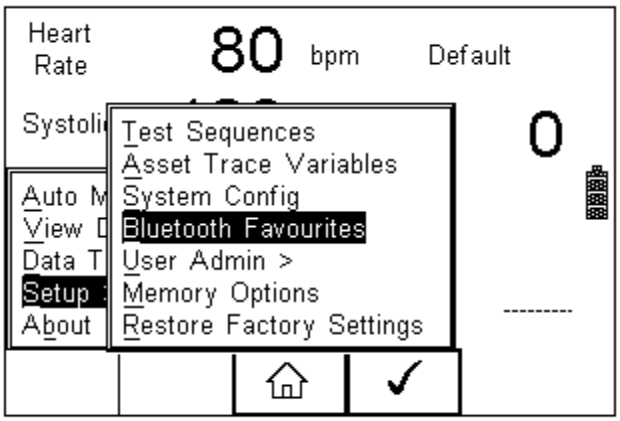
8.4 Bluetooth Favourites

In order for the Rigel UNI-SIM to automatically connect to the correct Bluetooth accessory, details of that accessory must be entered into the Bluetooth Favourites list.

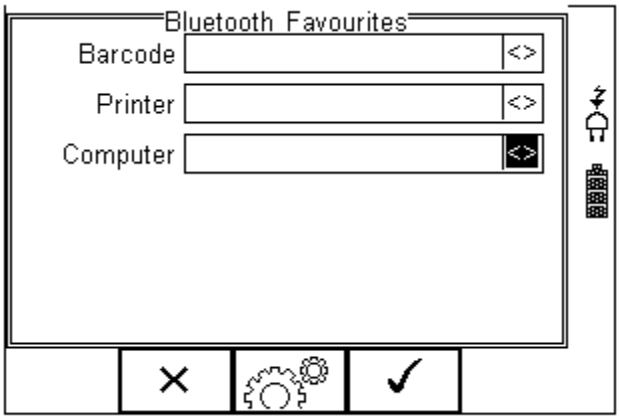
The Bluetooth Favourites list comprises of three sub-lists (device types), each of which can store up to 3 accessories of the same type. The three sub-lists are shown below:

- Barcode (Scanner)
- Printer
- Computer

To select Bluetooth Favourites, press the → button (F4) followed by Setup in the Menu and Bluetooth Favourites from the list as shown below. Press ✓ (F4) to select;



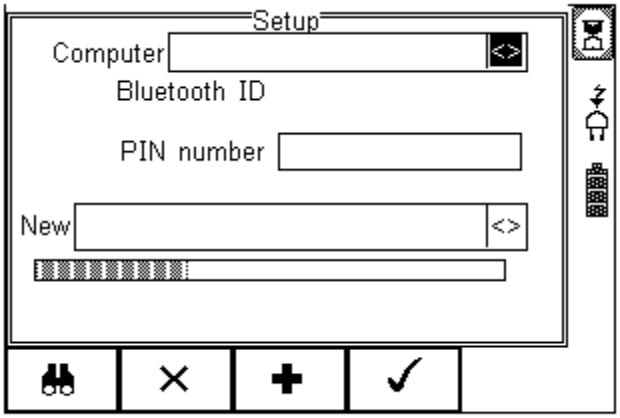
The following shows how to add a Computer to Bluetooth Favourites.



Use the up/down arrow keys to highlight the device type (in this case Computer) then press (F3).

Make sure that the device you want to add to your new favourites is switched on.

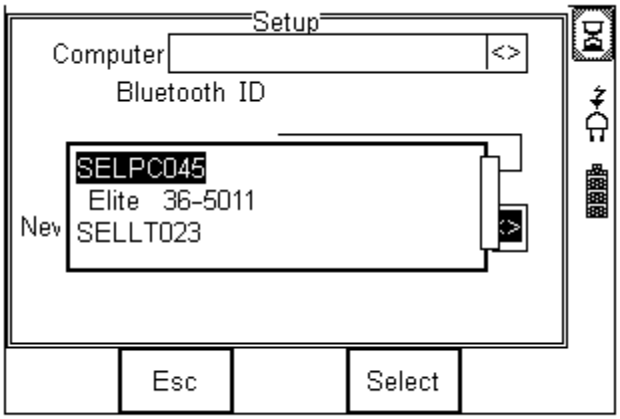
Press (F1). The Rigel UNI-SIM will search for all discoverable Bluetooth devices within a 10m range. The time taken to perform the search will vary depending on the number of Bluetooth devices in range. A progress bar will show during the search. When the search is completed, the progress bar will disappear.



Use the arrow keys to highlight the field labelled “New” and press the left or right keys to open the list of devices which have been found during the search.

Note: ***If more than 10 Bluetooth devices have been found the list will show the last 10 devices found.***

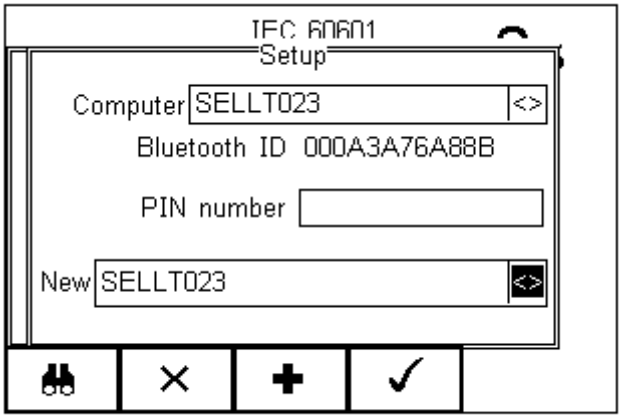
In the following example, the search has identified Bluetooth devices named “SELLT023”, “SELPC045” and “Elite 36-5011”



Note: ***If the required device is not shown, check that it is powered on with the Bluetooth function active then repeat the search.***

Note: ***Some Bluetooth devices do not report a recognisable name and may cause confusion when setting up Favourites. Turn off or disable unused Bluetooth devices when configuring Favourites.***

Use the up/down keys to highlight the required device (in this case SELLT023i) and press the ✓ button (F4). **SELLT023** is now placed in the “New” field as shown below.



Press ✚ (F3) to add SELLT023 to the Favourite Computer list.

To add further devices to the list of available computers select the new field again, use the up, down, left and right keys to select the required device and press ✚ (F3) to add the chosen device.

“SELLT023” has been added to the Computer field with **Bluetooth ID.**

Press ✓ (F4) to store the changes and return to the previous screen.

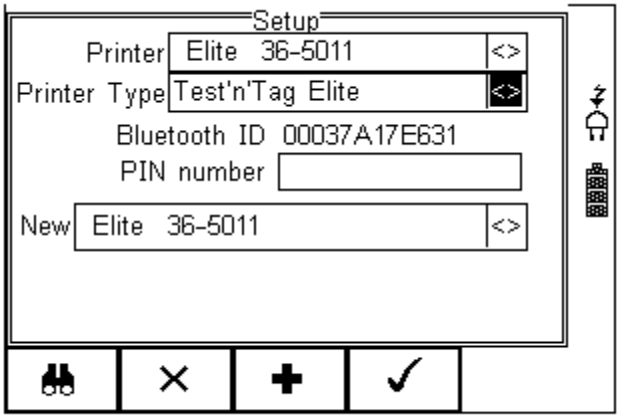
A PIN number can be entered if required for the device to be added to the Favourites list.

Note: ***Seaward and Rigel accessories do not require a PIN. For other Bluetooth devices refer to the manufacturer’s documentation.***

Note: ***Devices that are not required can easily be removed by selecting the Computer field, pressing the left of right keys to open the list, highlighting a device using the up/down keys and pressing*** 🗑 ***(F2). Confirm the deletion by pressing the*** ✓ ***button (F4). Press the*** ✓ ***button (F4) to save Bluetooth Favourites settings.***

All Bluetooth devices have a unique ID. The Bluetooth ID is shown when a device is added to the Favourites list.

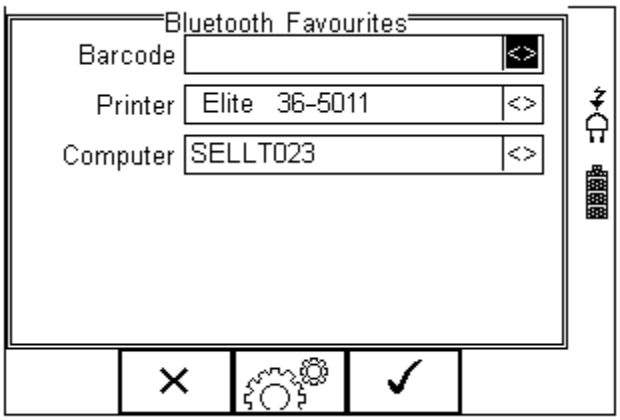
Repeat the actions above to select a printer for the UNI-SIM;



Ensure when selecting the printer, that the Printer type is selected corresponding with the print media:

Printer used	**BT ID**	**Printer type**
Test and Tag Elite	Elite 36-xxxx	Test ‘n’ Tag Elite
Citizen list printer	CITIZEN SYSTEMS	Citizen CMP/10
Test and Tag	SW T’nT (xxx-xxxx)	Test ‘n’ Tag

Press ✓ (F4) to store the changes and return to the previous screen.



“SELLT023” and “Elite 36-5011” are now a Bluetooth Favourite and the Rigel UNI-SIM will automatically establish a connection with “SELLT023” when using functions that communicate with a computer e.g. downloading records to a PC database software package or connect to “Elite 36-5011” when requiring a print-out.

Note: Press ✕ (F2) to exit without saving changes.

Press (F3) if necessary, to select another device..

Press ✓ (F4) button to save changes.

When all your favourite devices have been set up, press ✓ (F4) and they will be saved.

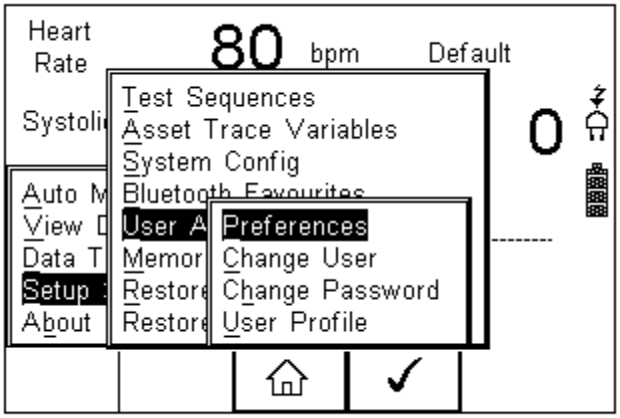
8.5 User Admin

The User Admin feature allows the user to personalise the way in which the tester behaves during normal use and include features such as:

- Preferences (see 8.5.1)
- Change User (see 8.5.2)
- Change Password (see 8.5.3)
- User Profile (see 8.5.4)

To enter the User Admin feature, press the button (F1) from the home screen, select Setup followed be User Admin.

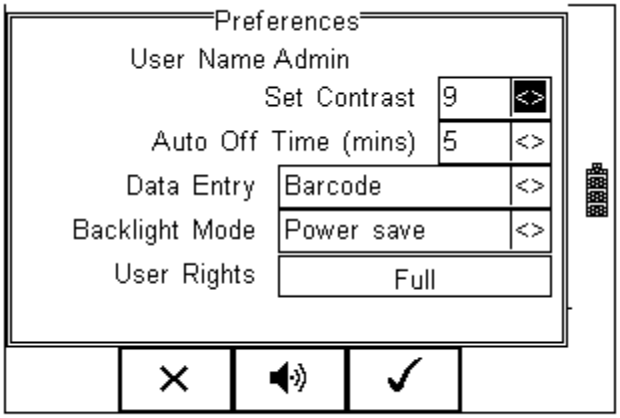
The following menu will appear:



Navigate through this menu using the Up & Down Keys and select by pressing the ✓ button (F4) or the right arrow key.

8.5.1 Preferences

Provides means of configuring the default settings of the tester's behaviour during normal use. All settings are user specific and stored against the logged-in user :



- **Set Contrast** – Use the up, down, left and right keys to set the contrast

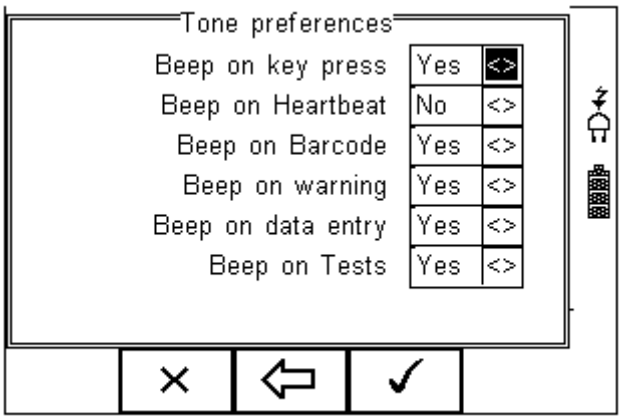
- **Auto Off Time (mins)** - Use the up, down, left and right keys to set the power off time on the tester. Settings between 0- 10 minutes. Note 0 minutes will deactivate the AutoSwitch Off feature.

- **Data Entry –** Sets the tester up to take data entry from Barcode or Keypad only. Use the up, down, left and right keys to select Barcode or Keypad only.
  Note: ***In data entry mode the unit will automatically try to connect to a barcode scanner via the internal Bluetooth module – if the scanner is available this feature will drain the batteries u-necessarily. In this instance it is recommended that the unit be set to Keypad only.***

- **Backlight Mode –** Chose between Always Off, Always On, Power Save (Back light on for 30 secs after each key press). Use the up, down, left and right keys to select.

- **User Rights** – For information only. To change the user rights, see 8.5.4

The (F2) button allows the user to set the audible warnings and beep on key presses. See menu below:



Navigate using the Up & Down Keys and change between Yes / No using the left key.

Confirm the settings using:

- ✓ *button (F4) this will return to the Home screen*
- ⇦ *button (F2) will return to previous menu and save data.*
- ✕ *button (F3) will return to the home screen without changes being saved.*

8.5.2 Change User

This feature allows an operator to default to a different existing user or setup a new user. Admin rights are required for this feature. Alternatively, new users can be created in the User Profile menu, see below.

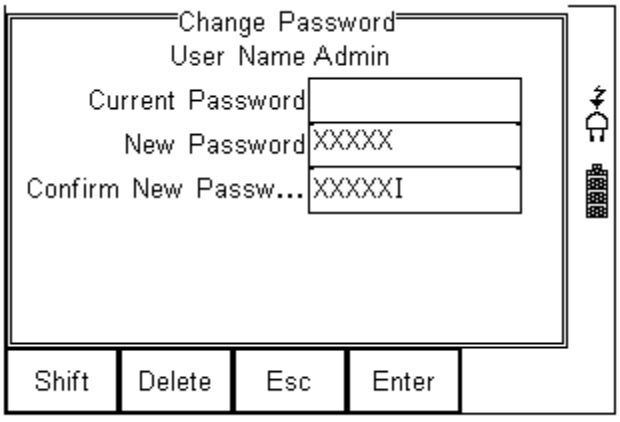
Note A brand new Rigel UNI-SIM will automatically default to admin rights so new users can be created.

8.5.3 Change Password

This feature allows a new password to be assigned or changes to an existing password.

To create a new password, highlight the New Password field using the Up & Down Keys and enter a new password followed by confirmation of the new password. Use the ⟵ key (F4) to finish and press the ✓ button (F4) to confirm and save the new password.

To change an existing password, enter current password and repeat the steps above. See menu below for an overview of the Change Password screen.

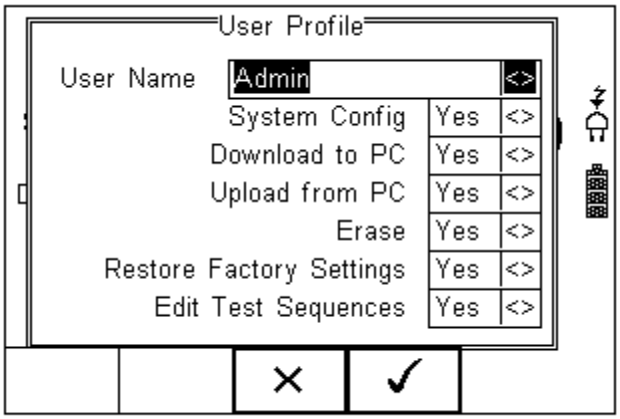


8.5.4 User Profile

This feature allows the administrator to setup new and existing users and inhibit or assign certain feautures to individual users.

Note that the User Profile is only valid when the ADMIN user has been setup with a PASSWORD. See item above. If no ADMIN password has been set, all users have FULL User Rights.

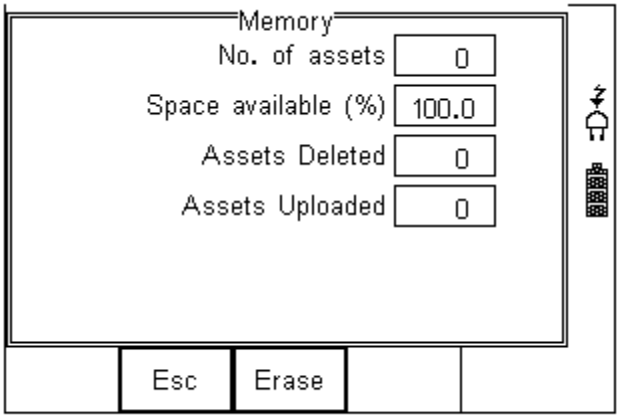
Select the applicable user name, use the Up & Down Keys to navigate through the menu, use the Left & Right Keys to activiate (yes) or de-activate (no) certain features. See menu below.



Press the ✓ button (F4) to save user profile.

8.6 Memory options

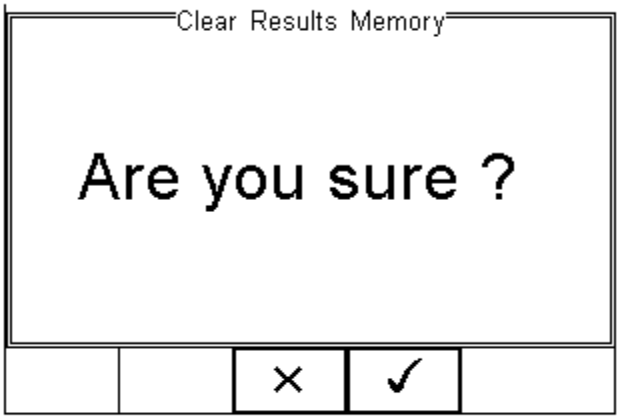
This feature is used to view information about the Rigel UNI-SIM memory status. Press (F4), select setup using the up/down keys and select Memory Options by pressing the press ✓ (F4) to accept.



The display shows the number of asset records currently stored, the remaining memory space, number of assets deleted and number of assets in upload memory.

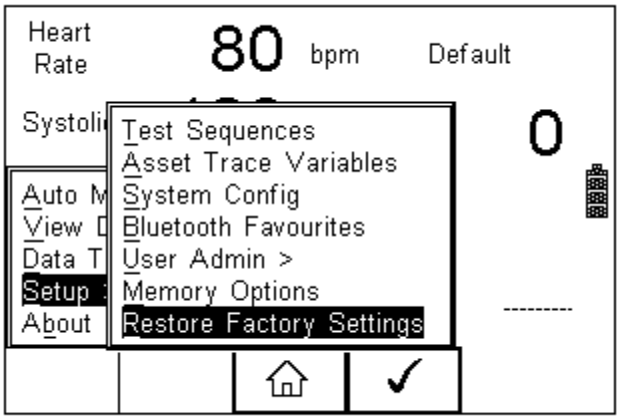
The nature of Flash memory is such that when records are deleted only the reference to the data is removed. The data still remains and will use memory space. The memory must be erased in order to release memory used by deleted records.

If the Erase (F2) key is pressed, a prompt is shown below. To erase the memory press ✓ button (F4).



8.7 Restore Factory Settings

The factory settings can be restored at any time using this function. Press button (F4). Select Setup followed by Restore Factory Settings.



All the settings provided within the Setup menu will default to Factory Settings including; All Asset Trace Variables, Test Sequences, User Admin, Test Codes and System Config.

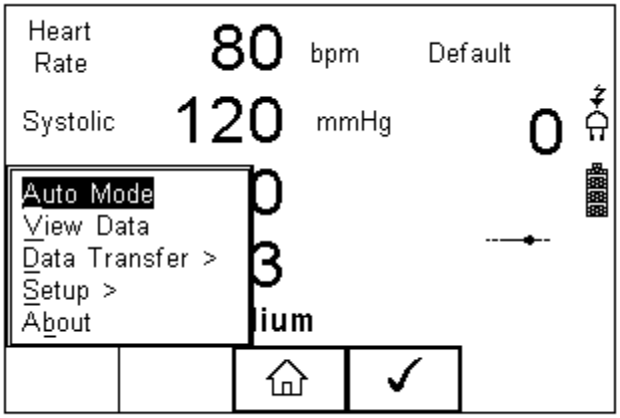
Warning: Restore Factory Settings cannot be undone and will remove all the customised items described above.

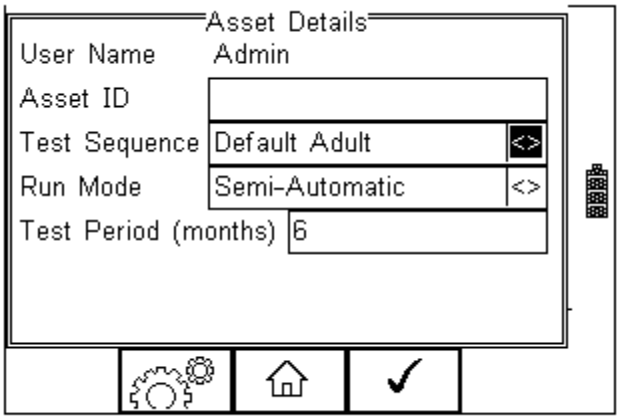
Hint; All customised settings within Setup can be cloned to a PC. We advise that this is done on a regular basis to ensure custom settings are saved for back-up. See 7.4 for further details on Cloning.

9 Automatic Mode

The Automatic mode provides the user with the ability to run a preset test sequence and store the data afterwards.

Press (F4), select Auto Mode using the up/down keys, Select by pressing the press (F4) to accept.





Asset ID

Each test record is stored using the Asset ID number (25 character max) and date / time of test. Multiple entries can be applied using the same Asset ID number. In this case, the memory will hold all entries and differentiate using the test date.

Test Sequence

Choose a selection of default and custom made test sequences. A total of 50 preset test sequences can be stored to meet specific requirements. (See 8.1 more information on creating new test sequences)

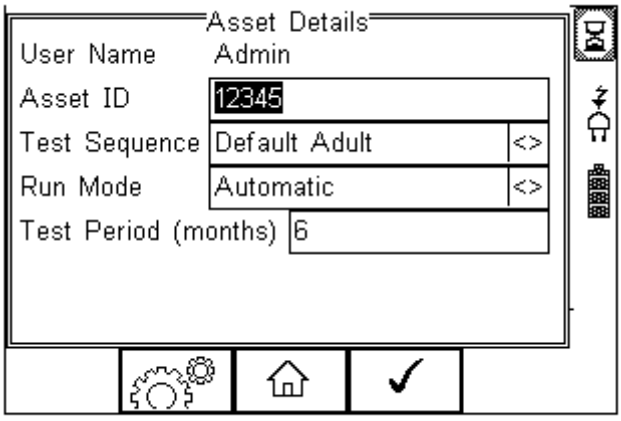
Run Mode

- Semi-Automatic allows the user the enter data after each individual test that forms a test sequence.
- Full Automatic will run through the test sequence and provides an opportunity to enter data at the end of the complete sequence.

Test Period

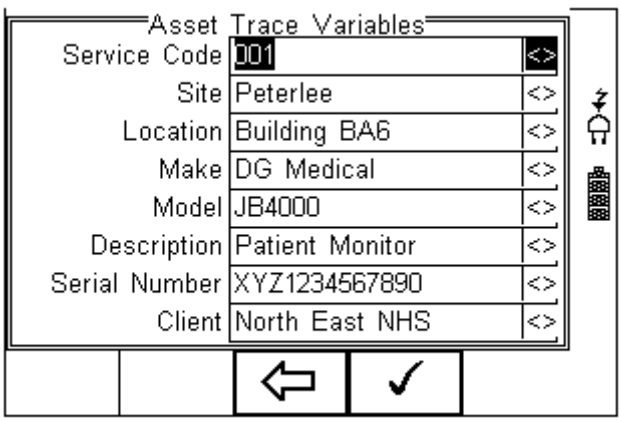
The re-test period allows the user to include the next test date on printed labels and PC downloads that make it easier to schedule future work. More details on printing labels see 9.2)

When all information is entered, press the ✓ (F4) to accept and continue to the next screen for Asset Trace Variables.



Asset Trace Variables

To increase the traceability of the safety test, the user can include valuable data with the test record such as Re-test period and Asset variables (see 8.2 for more information). Trace variables can be added once the above data has been entered and confirmed

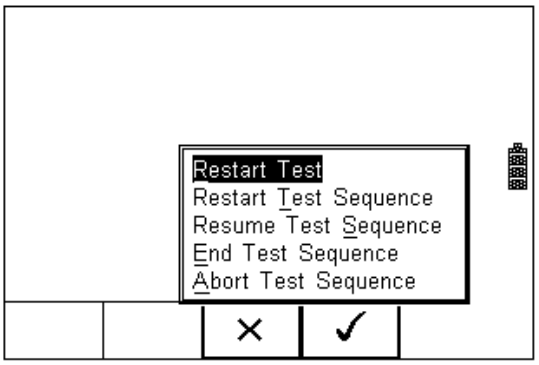


9.1 Performing an Automatic Test:

The automatic mode provides an option to test all available tests (inlcuding SPO2, NIBP, ECG, temperature, respiration and IBP simulations as well as a system Leak test, Static pressure tests and Overpressure test) in an automatic sequence.

9.1.1 Failure Menu

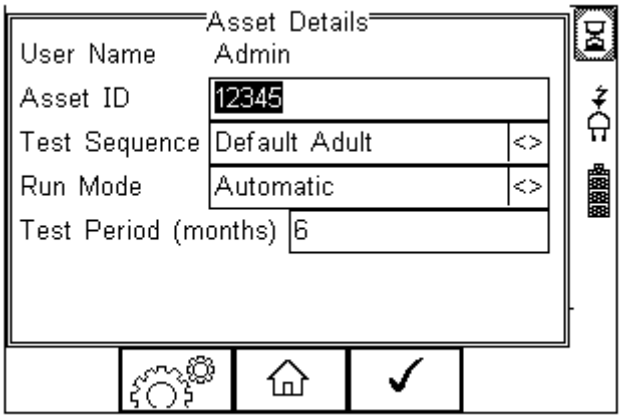
When a specific test fails, the user will be provided with a number of options depending on the nature of the fault. The Failure Menu will enable the user to:



- Restart Test (Individual test)
- Restart Test Sequence (Whole Test sequence)
- Resume Test (Skip the failed test)
- End Test Sequence (store result and follow options. See 9.3)
- Abort Test Sequence (no information stored, return to home screen)

The following procedures describe the setup and completion of an automatic test sequence. The steps are applicable to all available test sequences. As example we describe a default test sequence.

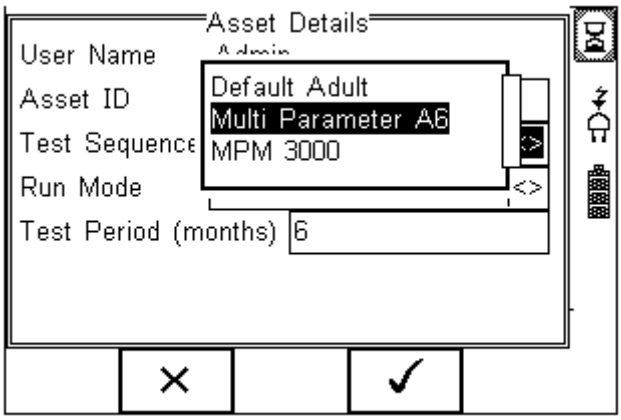
Press the button (F4) from the home screen and select Auto Mode. This will show the Asset Details screen as detailed below;



Select the right criteria for the Test from the Asset Details screen;

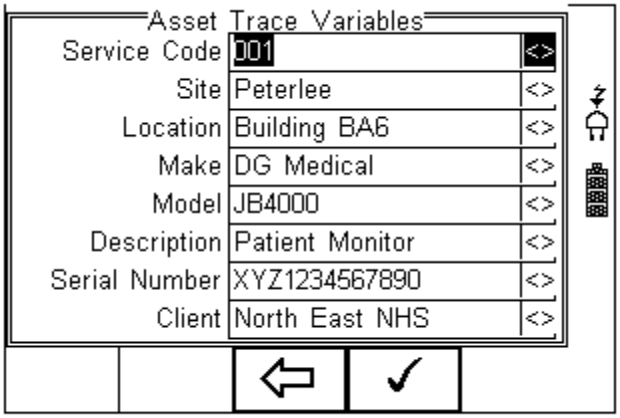
1. Enter the Asset ID number using the keypad or barcode scanner.
2. Enter the Test Code if this has been created (see 3.2)
3. Use the up, down, left and right keys to select the required Test Sequence

4. Enter the required test period in months.



5. Returning to the Asset Details screen, the button (F2) provides the user with the option to modify or create a new Test Sequence from this menu. This feature is identical to that of the Test Sequence feature in the Setup - Test Sequence menu. (See 8.1 for more information)

When all parameters are set, press the button (4) to enter the Asset Trace Variables screen (when applicable). In this example, all Asset Variables are activated.

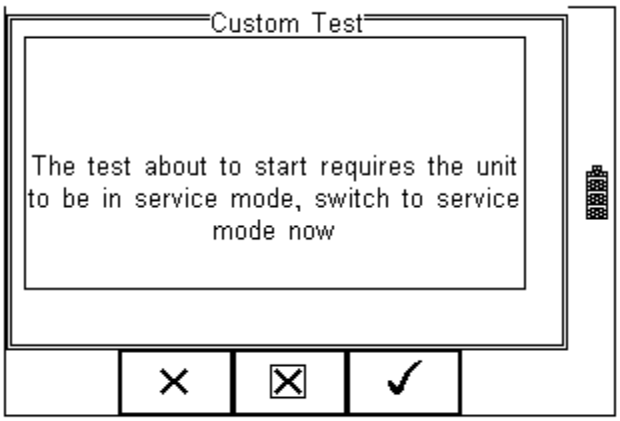


6. Use the Up & Down Keys to navigate the menu and the Left & Right Keys to open the drop down boxes [<>]. Select the required input and confirm with the button (F4). Each variable entered during the automatic test will automatically be added to the list for future use. Trace Variables that are de-activated (set to NO in the Setup menu, section 8.2) will not appear during the automatic tests.

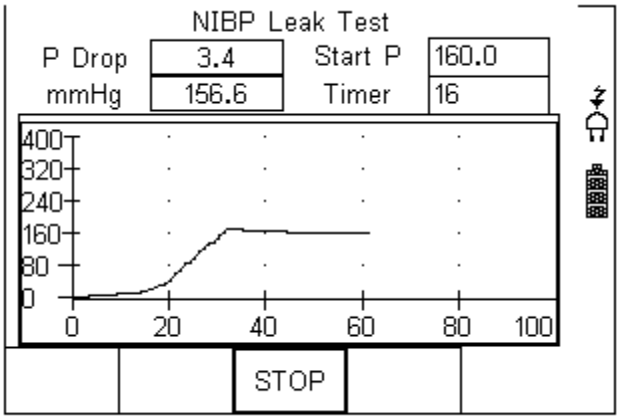
   Note that a maximum of 40 individual entries are available for each Trace Variable. Additional entries will overwrite on a first in first out basis.

When all information is provided, press the button (F4) to start the safety test.

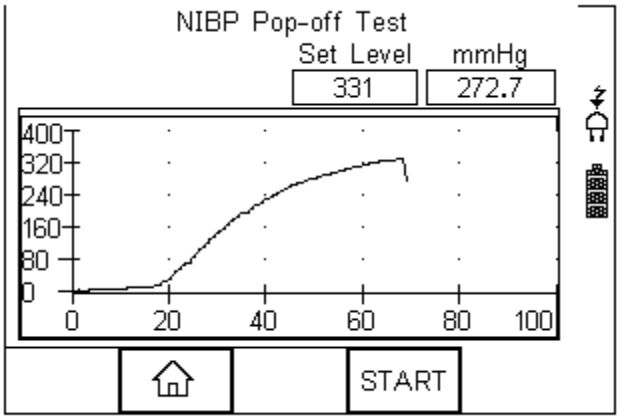
After an initial message:



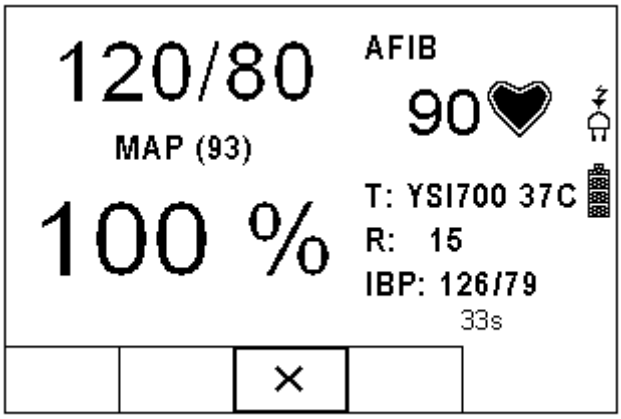
The first test of the Default test setting is the the NIBP Leak Test



Following the Leak test, the overpressure valve is tested;

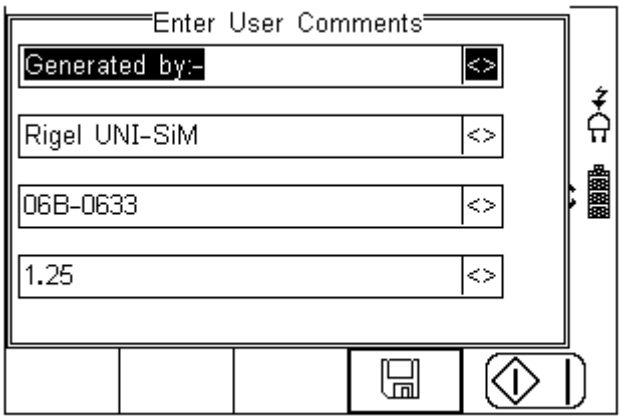


Following the Overpressure valve test, the UNI-SIM is ready to make all simulations as per the test routine;



Pressing the ✕ (STOP) button (F3) during any test will bring up the failure menu (see 9.1.1)

At the end of the test, the user has the ability to enter comments. See 8.3.3 for more information on how to activiate comments after a test.



Press the 🖫 button (F4) to store the comments.

Depending on the settings in Menu - Setup - System Config (see 8.3.2) , a number of After Test options are possible;

- **New Test** – Automatically brings up the next test screen.
  No further options or viewing of results available

- **Download** – Automatically down loads the test results to the PC (see 7.1)
  No further options or viewing of results available. The tester will return to the home screen.

- **Print Label** – Automatically prints the test results to a thermal printer.

No further options or viewing of results available. The tester will return to the home screen.

- **Test ‘n Tag** – Automatically prints a Test ‘n Tag label. (see 4.2)
  No further options or viewing of results available. The tester will return to the home screen.

- **Options Menu** – Provides a menu to allow further choices after a test. (see 4.3)

9.2 Test ‘n Tag

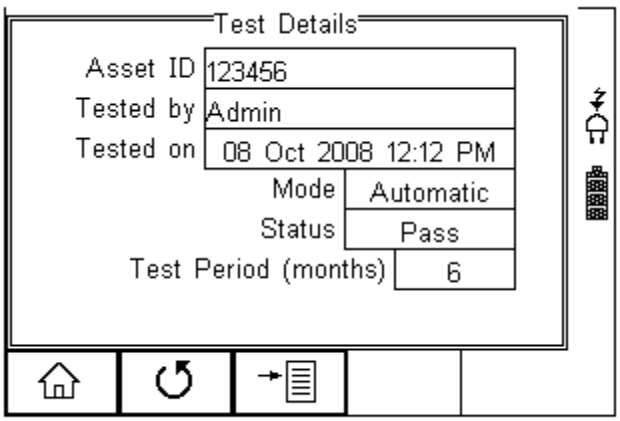
The Rigel UNI-SIM is compatible with the Seaward Test ‘n Tag and Test ‘n tag Elite system To use the Test ‘n Tag printer, add your T’nT printer to the Bluetooth Favorites. See 8.4

A detailed application note is available from the Rigel website on the used of Test’ n Tag printers with the Rigel UNI-SIM.

Please visit; http://www.rigelmedical.com/knowledgebase/

9.3 Options Menu

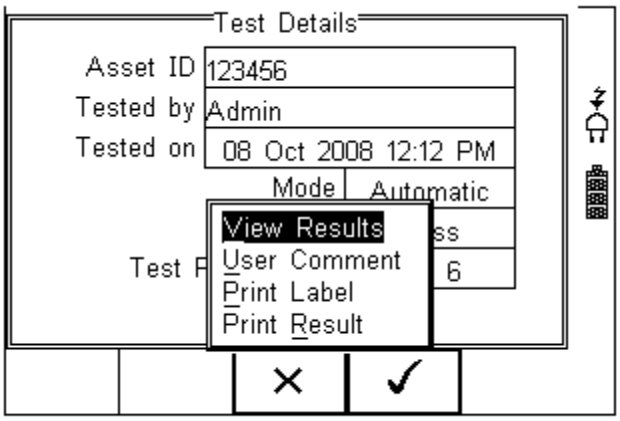
When Options has been selected in the Setup - System Config menu, the Rigel UNI-SIM will show a Test Details screen, see below.



The test screen provides the following features;

- Go to the home screen (F1)
- Continue with the next test (F2)
- Options (F3)

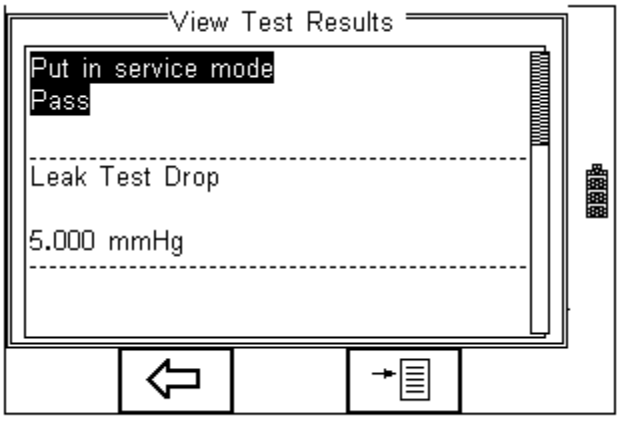
To view the options menu, select the button (F4) from the test details screen;
The options menu provides the following sub menu:



View Results will display the results of the test (see section 9.4)
User Comment will allow the user to enter comments if required
Print Label will print a pass/fail label on the thermal printer (50 mm roll)
Print Result will print the result on the thermal printer (50 mm roll)

9.4 View Results

Press the View result Button to review the data. Use the Up and Down keys to scroll through the screen.

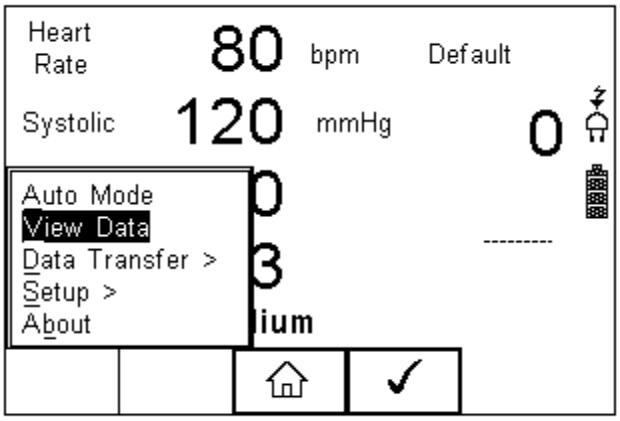


Use the ⇦ button (F2) to return to the Test Details screen.

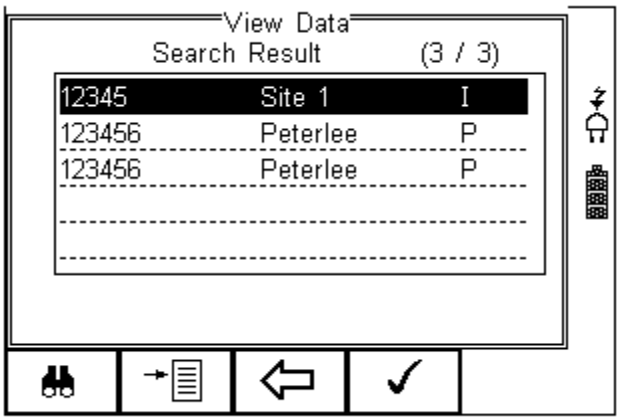
The →📄 button (F4) provides extra option to print results, label or Test ‘n tag

10 View Data

To view the stored data, press the button (F4) and select View Data from the menu;

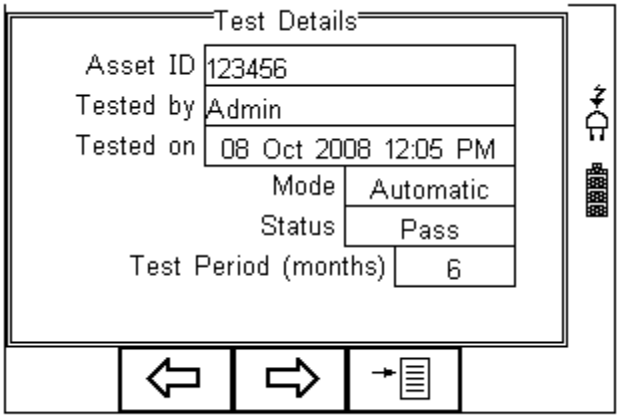


The following screen provides an overview of all available records in the memory, identified by Asset ID, Site and Pass or Fail.



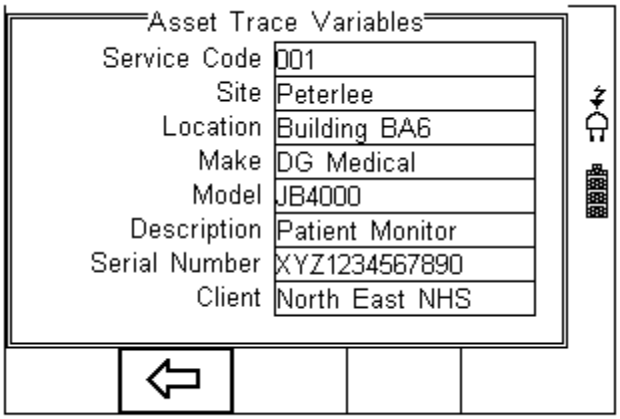
Use the up and down arrow keys to scroll through the database. When the desired record is highlighted, press the ✓ button (F4) to enter the record and view the data.

This will display the Test Details Screen



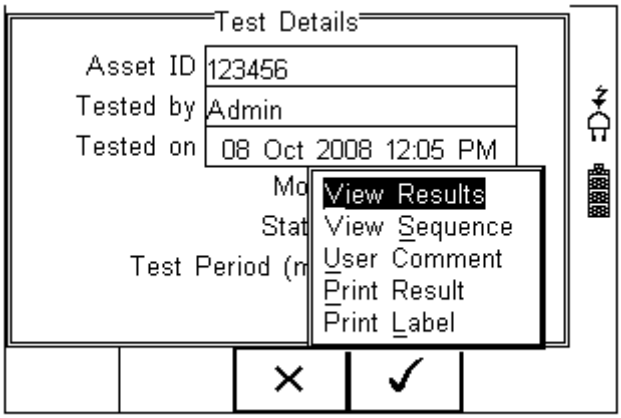
Use the ⇦ button (F2) to return to the main View Data screen.

Use the ⇨ button (F3) to view the Trace Variables;



Use the ⇦ button (F2) to return to the main View Data screen.

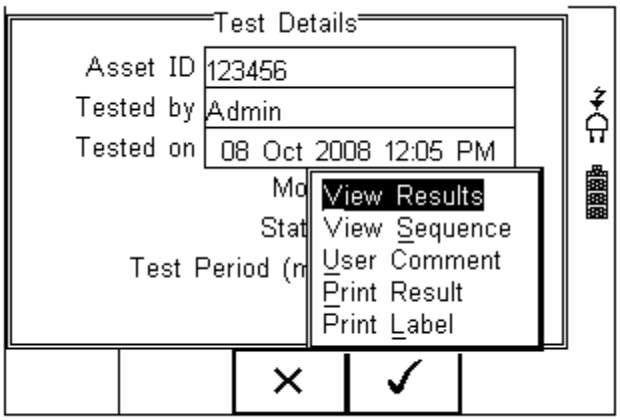
In the Test Details screen, press the →📄 button (F4) to view the following options:



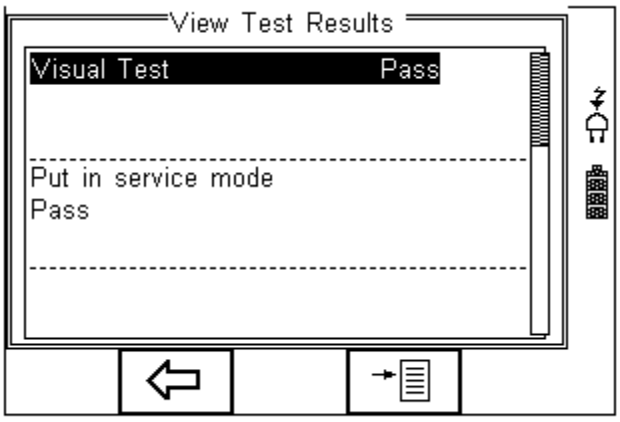
- **View Results** will display the results of the test (see section 10.1)
- **View Sequence** will display the test Sequence
- **User Comment** will allow the user to enter comments if required
- **Print Result** will print the result on the thermal printer (50 mm roll) (see Appendix D)
- **Print Label** will print a pass/fail label on the thermal printer (50 mm roll) (See Appendix D)

10.1 View Results

From the Test Details screen, select button (F4).

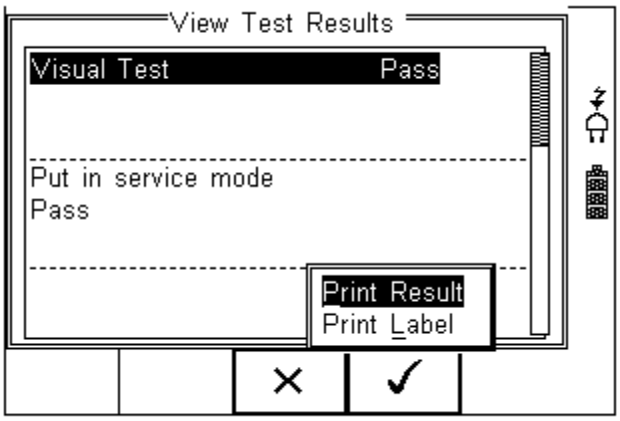


Use the up and down keys to select the view results option. Press the button (F4) to display the view text results screen (see below).



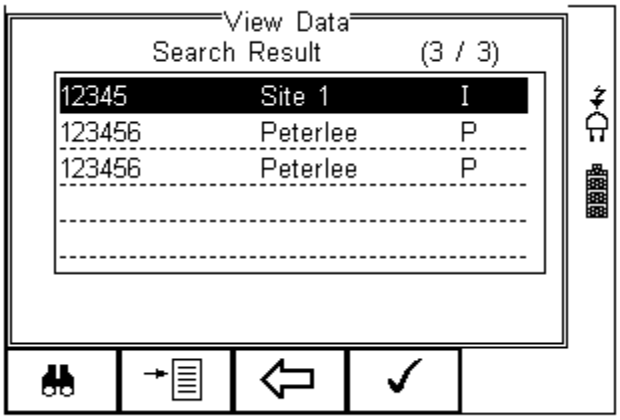
Use the button (F2) to return to main menu.

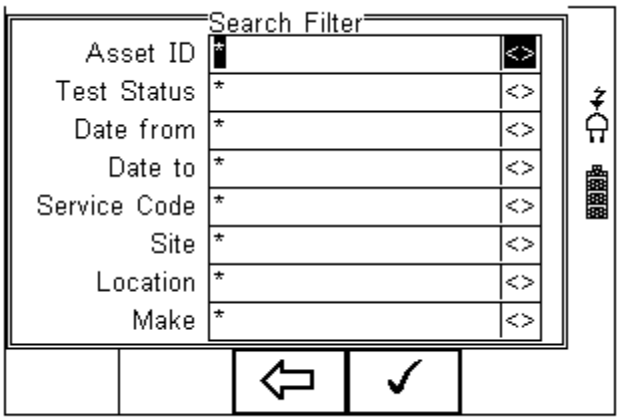
Press the button (F4) to provide the options to print the results;



10.2 Search the database

From the main View Data screen, press the button (F1).





Use the up, down, left and right keys to navigate this screen.

The default setting is '*' which includes all records that Passed.
To search for more specific criteria, fill in the required fields by either using the keyboard or drop down boxes.

Note ***The entered data must be identical to the data stored with the test. This includes visible and invisible SPACE characters.***

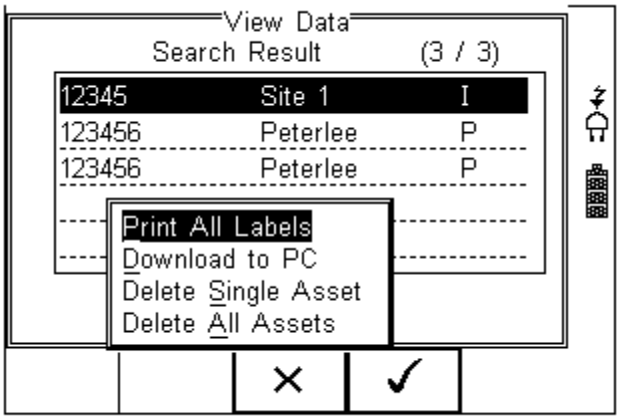
For Date entry use format DDMMYYYY or DD MM YYYY. For example for 31st October 2008 use 31102008.

Test Status Allows the user to select search criteria based on PASSED, FAILED or UPLOADED items.

To start the search, press the ✓ button (F4) or the ⇦ button (F3) to leave this screen.

10.3 View Data Options

From the main View Data screen, press the button (F2).



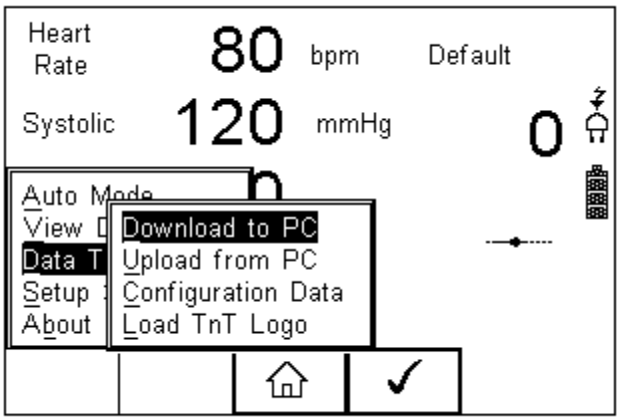
This will present an options menu to allow the user to:

- **Print All Labels** – Will download all records within the search criteria to the Test 'n Tag printer, setup in Bluetooth favourites.
- **Download to PC** – Will download all records within the search criteria to the PC, setup in Bluetooth favourites.
- **Delete Single Asset** – Will delete the single selected record.
- **Delete All Assets** – Will delete all records from the memory (this action is irreversible).

11 Data Transfer

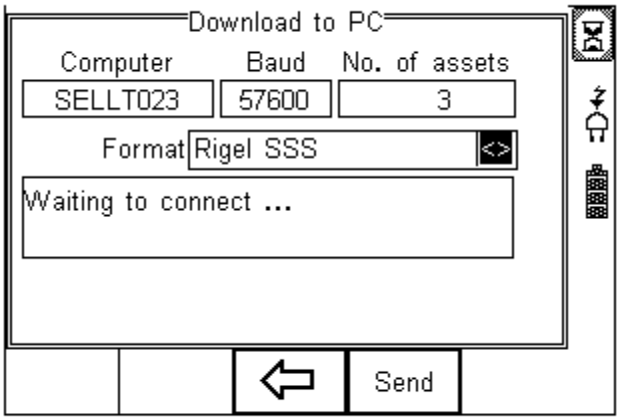
Data transfer is used to transfer records and configuration data to and from a PC load a logo in bitmap format for use with the Seaward Test ‘n’ Tag print system, and clone data.

The Data Transfer functions are accessed by pressing the button (F4), selecting **Data Transfer** using the up and down keys and pressing the button (F4).



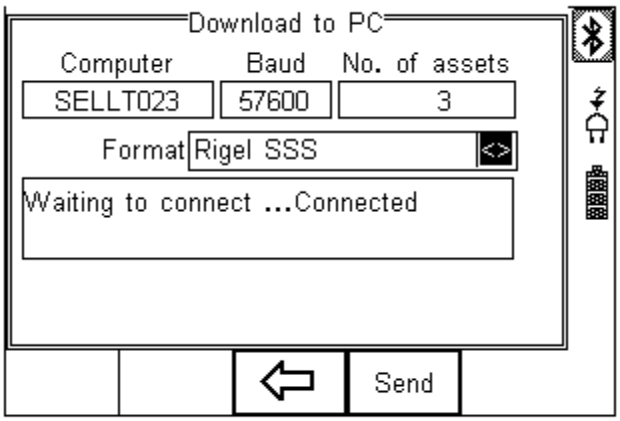
11.1 Download to PC

This feature is used to download records to a PC. Select Download to PC and press the button (F4) to accept. The Rigel UNI-SIM will now attempt to make a Bluetooth connection with the Computer that has been configured in the Bluetooth Favourites.



Initially, the Bluetooth status icon will display the egg timer for a few seconds, as shown

on the left, while the connection is established. When the connection is established and ready to communicate the Bluetooth status icon will change to show the Bluetooth icon as shown on the right.



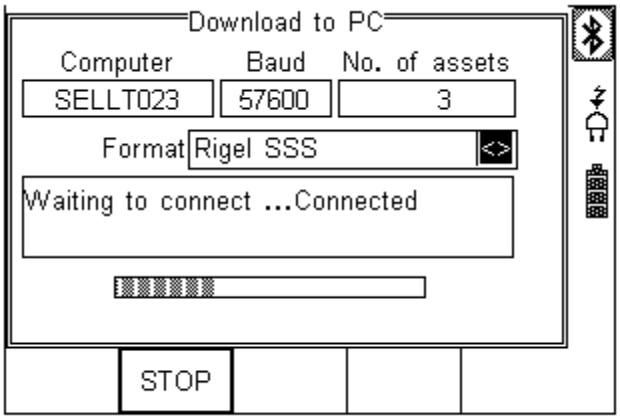
The Rigel UNI-SIM is able to download in a number of formats to suit individual requirements. These are;

- CSV Full (Comma Separate Value, download only)
- CSV Summary (Comma Separate Value, download only)
- Rigel SSS (Up and download format)

Toggle between the options by using the left and right arrow keys.

The Rigel UNI-SIM is now ready to transfer data. The No. of assets field shows the number of records that will be downloaded. Ensure that the PC application is ready to receive data then press the Send button (F4).

A progress bar, as shown below, will now follow the data transfer until download is complete.



Note **To download a selection of the database, refer to "View Data" (section 6). Search on the required criteria then select "download to pc" from the options menu.**

11.2 Upload from PC

This feature is only available when used in combination with the new Med-eBase PC software and when the SSS format is activated on your device.

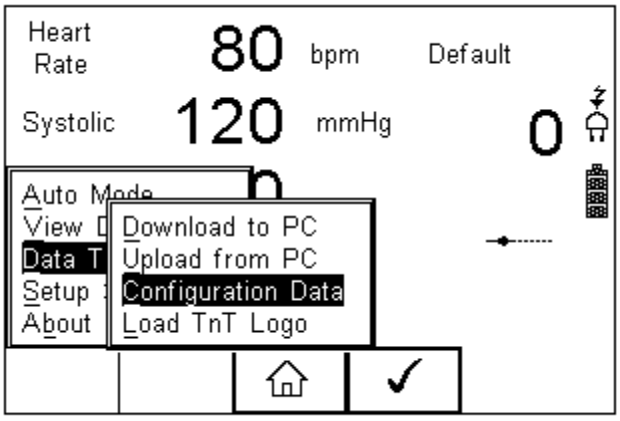
Select the Upload from PC option from the Data Transfer menu. The Rigel UNI-SIM will now attempt to establish a Bluetooth connection to the PC as previously described in Download to PC**.** The Rigel UNI-SIM is now ready to receive upload data from a PC. Refer to the Instruction manual of MediGuard plus on how to transmit data from the PC.

To activate the .SSS format on your Rigel UNI-SIM tester, please download the SSS Application note from our knowledge base.

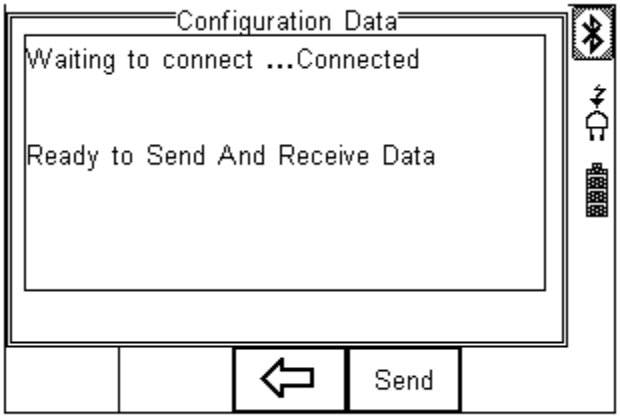
Please visit; www.rigelmedical.com/knowledgebase/

11.3 Configuration Data

This feature can be used to transfer store or modify the current Trace Variables, User Profiles and Comment lists to/from a PC. It can be used to configure a number of Rigel UNI-SIM units with identical Trace Variable, User Profile and Comment lists.



Once the UNI-SIM has connected to the PC, the Bluetooth icon will appear. Capture the data using the datatransfer.exe program or Windows hyperterminal.



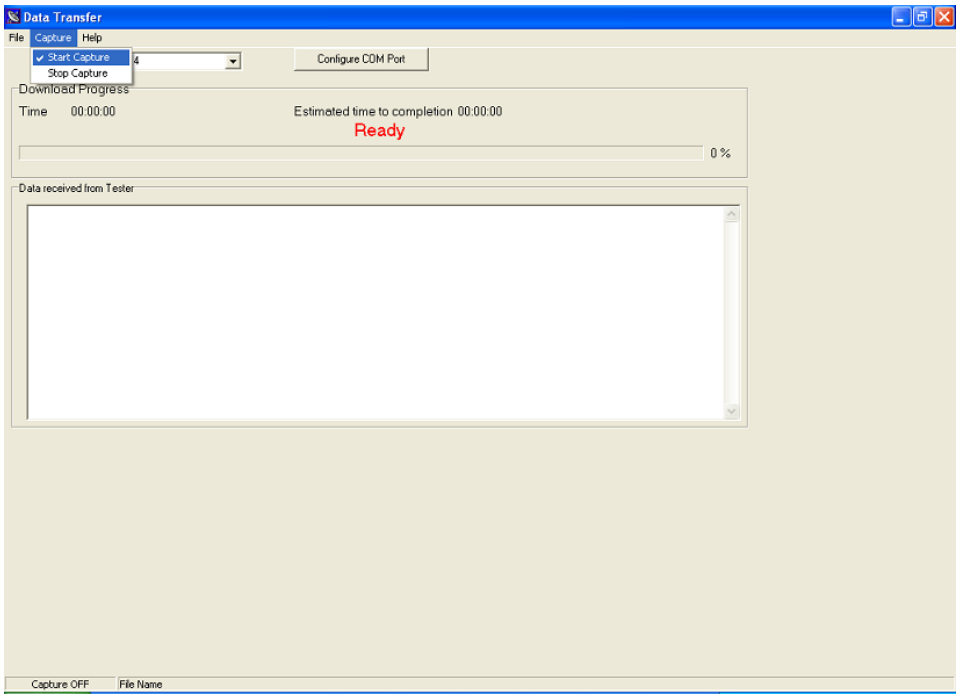
Press the SEND (F4) button to send data to the PC.

The UNI-SIM will automatically receive data when the ready message is shown as above.

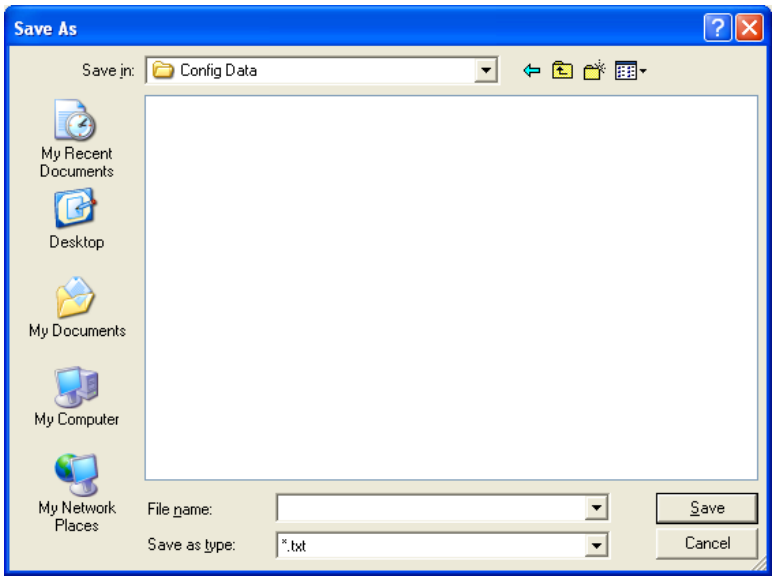
Press the ⇦ (F3) button to go back to the start screen.

Open the Bluetooth Downloader (Data Transfer.exe) application on your PC and check that the Com Port is correct for the Bluetooth USB adaptor being used with the P.C. The baud rate will default to the correct value of 57600.

In the application, select Start Capture from the Capture menu in the task bar.

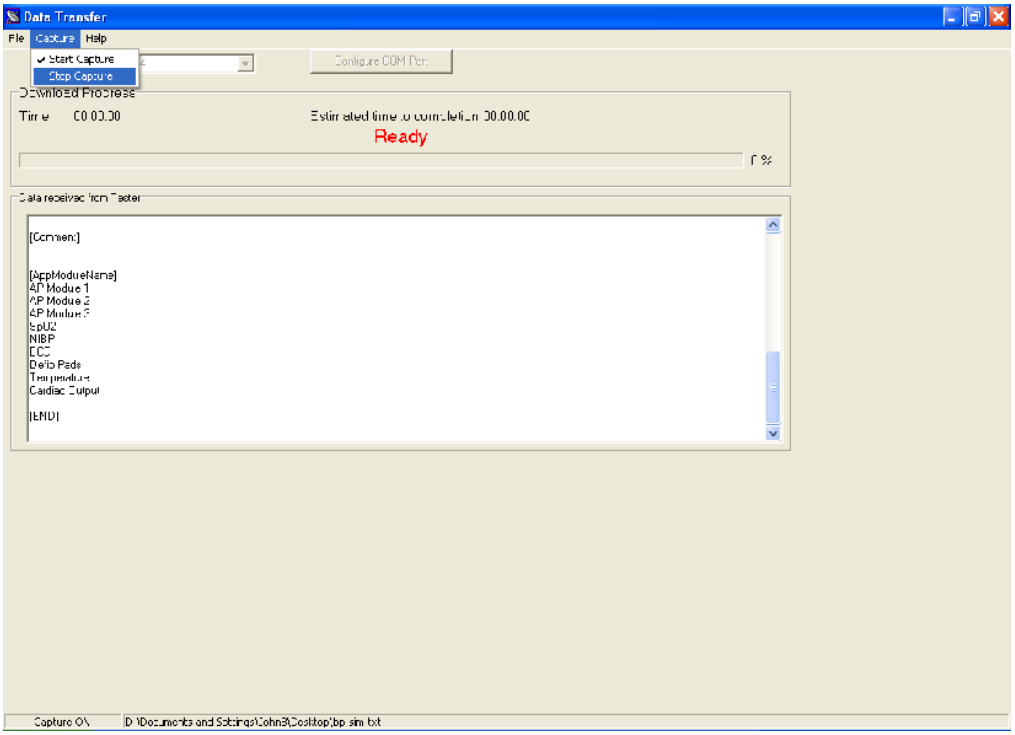


Enter a valid file name for the text file containing the download information; see below.



Once the text file has been created, press the Send button (F4) to transfer the Asset Trace variables and User names from the Rigel UNI-SIM to the PC.

The downloaded text will appear in the Bluetooth Downloader screen. Select Stop Capture from the Capture menu in the task bar. See below;



Close down the Application and open the text file using word pad or equivalent.

The downloaded information can be used to 'clone' other Rigel UNI-SIM's or modified to add additional trace variables. Again these can be uploaded to any Rigel UNI-SIM for convenience.

Note: ***The file transfer can be made using any suitable PC application such as the Seaward Bluetooth Downloader (Data Transfer.exe) or Hyperterminal capable of sending and receiving a text file.***

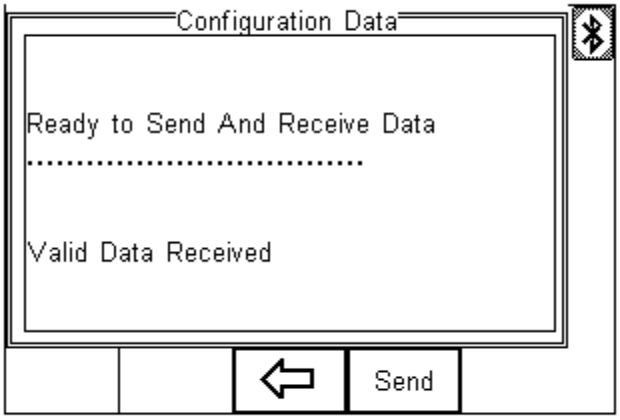
Note: ***The maximum number of entries for each field is SiteName (40), LocationName (50), UserName (40) and Comment (80).***

11.3.1 Receive Config Data

Follow the steps above in Send Config Data to run the Bluetooth Downloader and connect the Rigel UNI-SIM to your PC.

Click on File on the Bluetooth Downloader menu and select Send File. This will open a window allowing you to select the text file containing your Trace Variables, User Profiles and Comments configuration data. Select the require file and click on Open. The Bluetooth Downloader will now transfer the configuration file to the Rigel UNI-SIM.

When the transfer is complete the Rigel UNI-SIM screen will display a message as shown below.



If the transfer is not successful, check that the format of the configuration file exactly matches that specified.

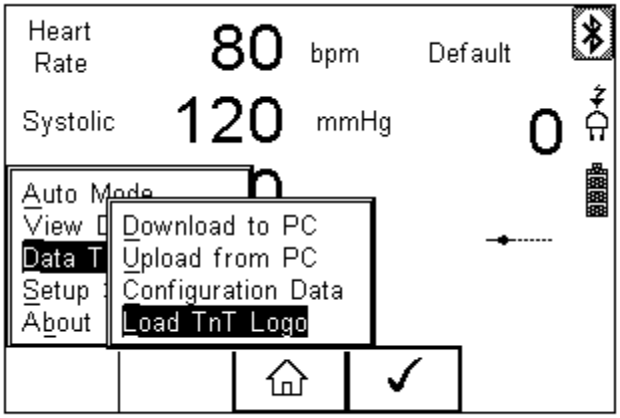
Note: ***The Config file must be ASCII text and the last entry must be the [END] statement.***

11.4 Load TnT Logo

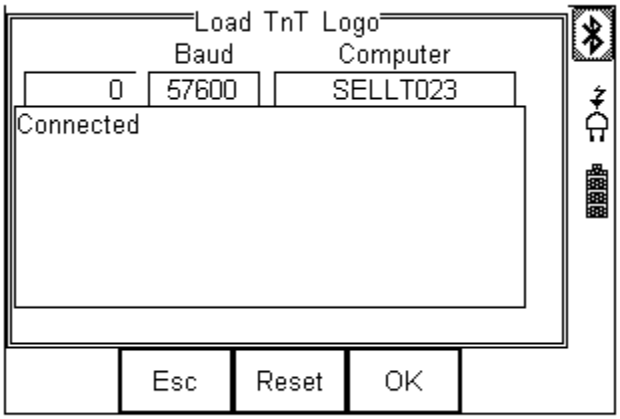
A bitmap logo can be transferred to the Rigel UNI-SIM for use with the Seaward Test ‘n’ Tag print system.

The logo must be in .BMP format with a maximum size of 320 pixels by 240 pixels.

Press button (F4), select Data Transfer using the up/down keys, select load T ‘n’ T logo and press the ✓ button (F4);



The Rigel UNI-SIM will now attempt to connect to the PC, setup in Bluetooth Favourites. When a connection has been established the display will be as shown below.



The Rigel UNI-SIM is now ready to receive data. The amount of data received is shown numerically on the top left of the display (0 in the screen shot above).

When using the Bluetooth Downloader application, select Send File from the File menu in the task bar. This will open a window allowing you to select the Bitmap file.
Select the required Bitmap and click on Open. The Bluetooth Downloader will now transfer the file to the Rigel UNI-SIM.

When the transfer is complete the Rigel UNI-SIM screen will display a message as shown below.

Press the ✓ OK button (F4) to save the logo. The logo is now available for printing using the Seaward Test 'n' Tag printer.

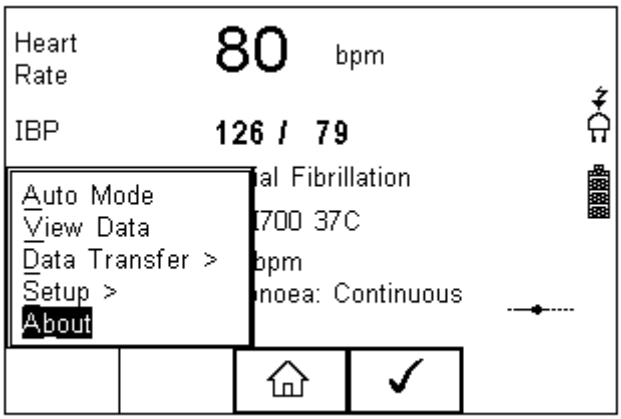
Note: ***The file transfer can be made using any suitable PC application such as the Seaward Bluetooth Downloader (data transfer.exe) or Hyperterminal.***

12 About

This screen provides details on the Rigel UNI-SIM's;

- Firmware version
- Hardware version
- Calibration status
- Last Calibration Date
- Serial Number
- Bluetooth ID

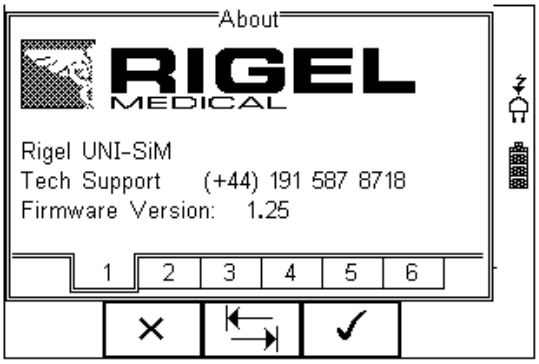
Select ABOUT from the menu below;

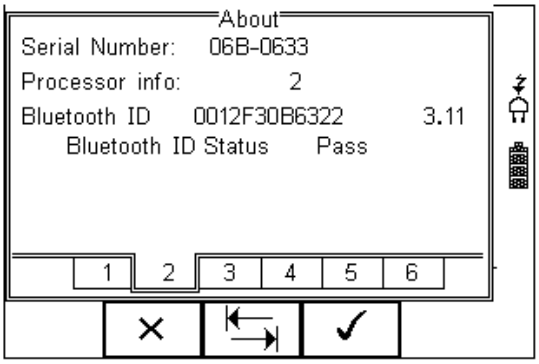


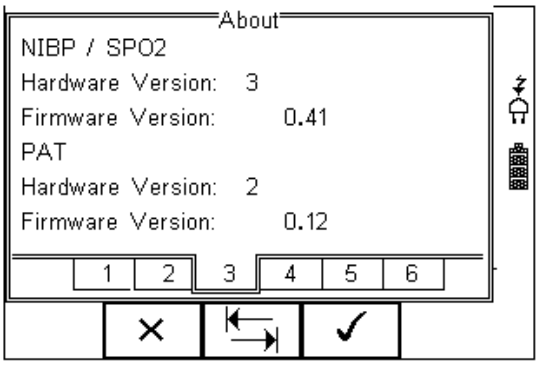
Use the scoll keys (F3) to toggle between the different information screens;

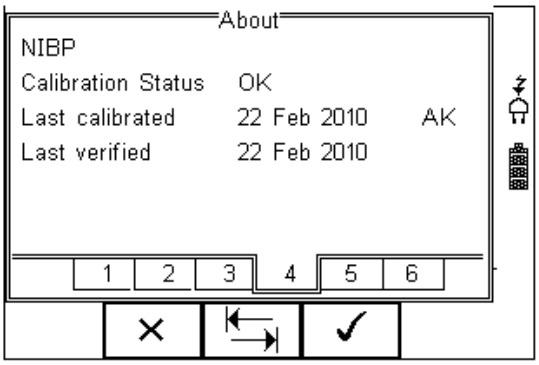
See next page.

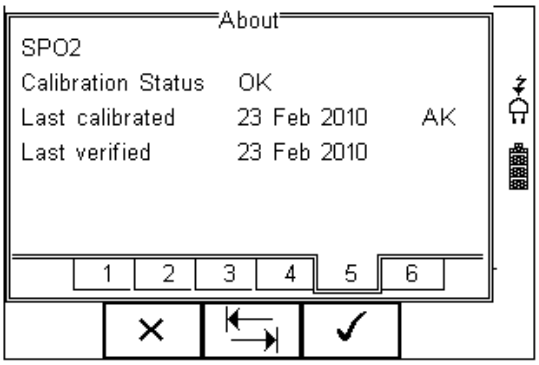
Ensure you have this information available when contacting Rigel Medical for Technical Support or Service. See chapter 9 for more information on Service and Calibration Procedures.

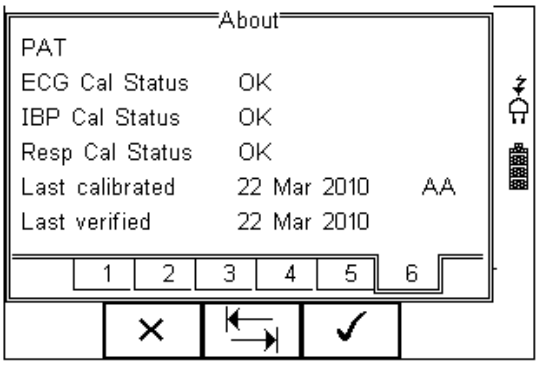

About
RIGEL
MEDICAL
Rigel UNI-SiM
Tech Support (+44) 191 587 8718
Firmware Version: 1.25
1 2 3 4 5 6


About
Serial Number: 06B-0633
Processor info: 2
Bluetooth ID 0012F30B6322 3.11
Bluetooth ID Status Pass
1 2 3 4 5 6


About
NIBP / SPO2
Hardware Version: 3
Firmware Version: 0.41
PAT
Hardware Version: 2
Firmware Version: 0.12
1 2 3 4 5 6


About
NIBP
Calibration Status OK
Last calibrated 22 Feb 2010 AK
Last verified 22 Feb 2010
1 2 3 4 5 6


About
SPO2
Calibration Status OK
Last calibrated 23 Feb 2010 AK
Last verified 23 Feb 2010
1 2 3 4 5 6


About
PAT
ECG Cal Status OK
IBP Cal Status OK
Resp Cal Status OK
Last calibrated 22 Mar 2010 AA
Last verified 22 Mar 2010
1 2 3 4 5 6

13 Maintaining the Rigel UNI-SIM

13.1 Cleaning the UNI-SIM

The Rigel UNI-SIM case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel or in the lead storage area.

Do not allow liquid inside the Rigel UNI-SIM or near the sockets. Do not use abrasives, solvents or alcohol.

If any liquid is spilt into the Rigel UNI-SIM case, the simulator should be returned for repair, stating the cause of the defect.

13.2 User Maintenance

The Rigel UNI-SIM is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.
If the Rigel UNI-SIM is subject to condensation, allow the Analyser to completely dry before use.

- Always check the Rigel UNI-SIM and supplied accessories for signs of damage and wear before use.
- Do not open the Rigel UNI-SIM under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance should only be performed by authorised personnel.
- There are no user replaceable parts in the Rigel UNI-SIM.
- The unit should be regularly calibrated (at least annually).

13.3 Return Instructions.

For repair or calibration return the instrument to:-

Rigel Medical
Service Dept.,
p.a. Seaward Electronic Limited.
Bracken Hill
South West Industrial Estate
Peterlee, Co. Durham
SR8 2SW, England

Tel : +44 (0)191 5878739
Fax: +44 (0)191 586 0227

sales@rigelmedical.com

calibration@seaward.co.uk

www.seaward.co.uk

www.rigelmedical.com

Prior to returning your unit for service, please contact our service department to obtain a Returns Number.

By obtaining a Returns Number, your service request can be booked in advance thus reducing the down time of your equipment.

When asking for a Returns Number, please quote:

- Instruments name and model
- Serial number (see section 8)
- Firmware version (see section 8)

Technical Specifications

Technical Specifications

Non-invasive Blood pressure Simulation

Waveform	Oscillometric
Pulse Volume	High, Medium, Low, paediatric
Heart rate	20 - 300 bpm
Integrated Pump	0 to 350 mmHg user configurable
Leak test	user configurable between 0-350mmHg
Chronometer	configurable upto 999 secs
Digital Manometer	0 - 410 mmHg
Pressure Accuracy	+/- 0.5% FS
Pressure Units	mmHg, inHg, kg/cm2, cmH2O, mBar, PSI, inH2O and kPa

Oxygen Saturation Simulation (SP02 Adapter boxes)

Simulation	Optronic (Electronic & Optical)
Simulation via	probe & full chain
Range	50 to 100%
Accuracy	± 0.5% of reading between 80-100% SPO2 ± 1% of reading between 50-79% SPO2
Heart rate	20-300 bpm
Accuracy	± 1 bpm
Compatible technology	GE - Datex, Nellcor, N.Oximax, Masimo,
Datascope,	Mindray, Nonin, Philips (HP)
Perfusion Index	0-20% (5% default)
Chronometer	test option to test response time SPO2 monitor.

Oxygen Saturation Simulation (PULS-R)

Range	30 to 100%
Repeatability	± 5%** of reading between 30-59% SPO2 ± 3% of reading between 60-99% SPO2 ± 3% of reading between 90-100% SPO2

Accuracy of simulation when used with the corresponding R-curves
*Based on using the same probe and monitor setup
**Note that some monitor types might not be able to display low range sats

Heart rate	30-300 bpm***
Accuracy	± 1 bpm
Compatibility	Beijing Choice, Criticare, GE Tuffsat, Masimo, Mindray, Nellcor, Nellcor Oximax, Nihon Kohden,

Nonin, Novametrix, Philips / HP

***Subject to monitor capability

ECG Arrhythmia Simulator

Simulation	5 lead simulation including high level output on Normal Sinus Rhythm (NSR), ST Elevation, ST Depression, Myocardial Infarcation, Tall T
Heart rate	20 – 300 BPM
Accuracy	±1 BPM
Amplitudes	0.5 / 1 / 1.5 / 2 / 2.5 / 3 / 3.5 / 4 / 4.5 / 5 mV.
Accuracy	±2%
Connection high-level ECG	3.5 mm jack plug

ST Elevation / Depression

Heart rate	20 – 300 BPM
Elevation %	7%, 13%, 20%
Elevation slope	positive, negative, flat

Myocardial Infarction

Type	Ischemia, Injury, Infarction, Inferior Infarction
Heart rate	20 – 300 BPM

Tall T

Heart Rate	80 bpm
T wave Amplitude	0 – 1.2mV (steps of 0.1mV)

Arrhythmia Waveforms (Atrial)

Simulation	full 12 lead simulation
Amplitudes	0.5 / 1 / 1.5 / 2 / 2.5 / 3 / 3.5 / 4 / 4.5 / 5 mV.
Heart rate (where applicable)	20 – 300 BPM

Atrial

Sinus Arrhythmia (SA), Missing beat, Atrial Flutter (AFLT), Atrial Fibrillation (AFB), Paroxysmal Atrial Tachycardia (PAT), Junctional Premature Contraction

Atrial Conduction

First Degree AV Block, Second Degree AV Block - Mobitz I, Second Degree AV Block - Mobitz II, Third Degree AV Block, Right Bundle Branch Block (RBB), Left Bundle Branch Block (LBB), Left Anterior Hemiblock

Ventricular

Premature Ventricular Contraction - Intermittent Premature Ventricular Contraction – Continuous, Bigeminy, Trigeminy, Ventricular Flutter (VFLT), Ventricular Fibrillation Fine (VFBF), Ventricular Fibrillation Coarse (VFBC),Monomorphic Ventricular Tachycardia (MVT), Polymorphic Ventricular Tachycardia (PVT) Right Focal (PVC).

Performance Waveforms

Shape	Sine, Square, Triangle, and Pulse
Rates	0.1 to 0.9Hz (in steps of 0.1) 1 to 100Hz (in steps of 1)
Amplitudes	0.5 / 1 / 1.5 / 2 / 2.5 / 3 / 3.5 / 4 / 4.5 / 5 mV.
Pulse	1mV, 4 sec delay (20ms pulse duration)

Pacer Waveforms

Available	synchronous atrial, asynchronous atrial, paver only, ventricular pacer, atrial & ventricular pacer
QRS	1mV
Pacer Pulse Amplitude	0.1 – 2 mV
Pacer pulse Polarity	positive, negative
Pacer pulse width	0.1 – 2ms

R Wave Detection

Heart Rate	70 bpm
R wave width	10 – 120 ms (steps of 10ms)

Temperature Simulation

Simulation	YSI 400 / 700 Static
Range	preset at 25, 33, 37and 41°C
Accuracy	±0.1 °C
Default setting	YSI 400 37°C

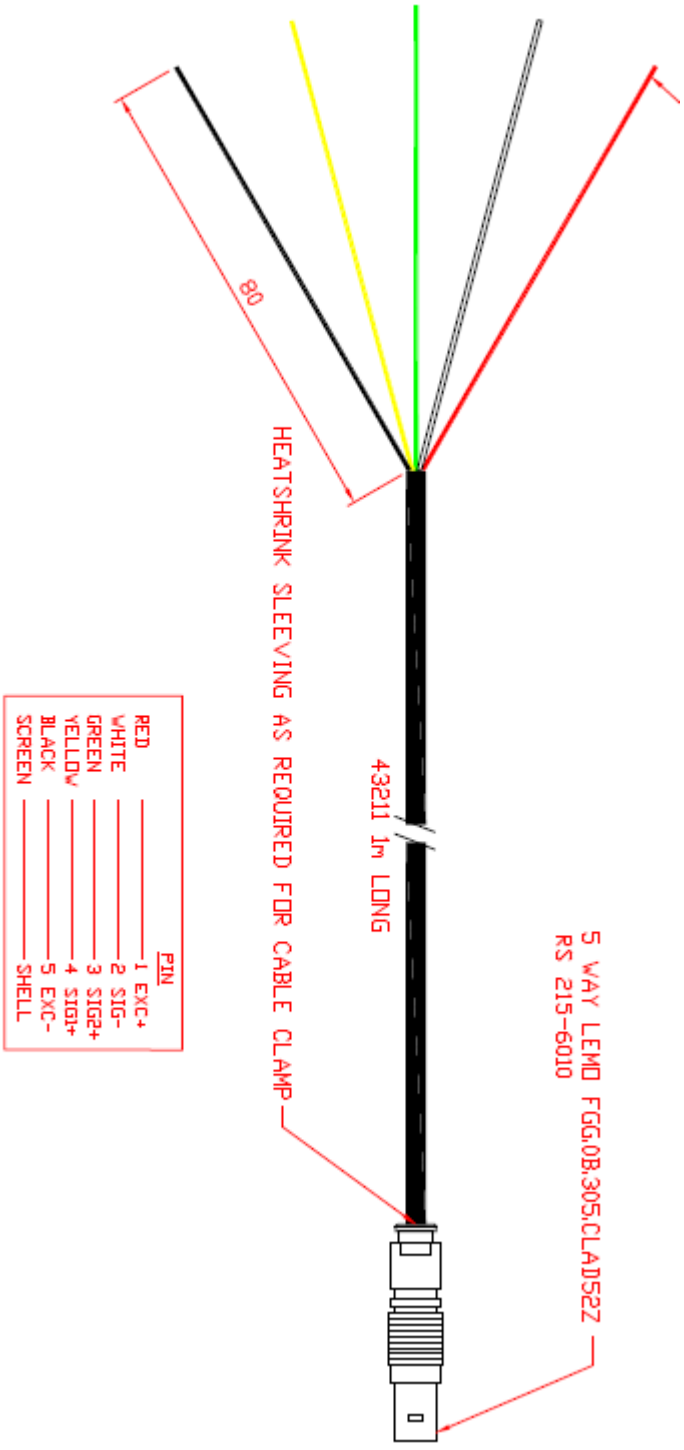
Respiration Simulation

Rates	5, 10, 15, 30, 60, 120, 180 Breaths per Minute
Base resistances	250, 500, 750, 1000 ohms
Accuracy	±5%
Resistance Variations	0.1, 0.5, 1.0, 1.5 ohms
Accuracy	±10%
Default Settings	15bpm / 250Ω / 0.1Ω
Apnoea Simulation	0 – 60 seconds duration 0 – 300 seconds interval.

Appendix A Firmware Route Map

Manual Mode	*NIBP*	**NIBP Test Settings**
		NIBP Leak Test
		NIBP Static Pressure Test
		NIBP Pop-off Test
		NIBP Manometer Mode
		Set Zero
	SPO2	**SPO2 simulation settings**
	PAT	**Patient Test Settings**
		Static IBP Test
		Performance Wave forms
Auto Mode		
View Data		
Data Transfer	*Download to PC*	
	Upload fro PC	
	Configuration Data	
	Load T'nT Logo	
Setup	*Test Sequences*	
	Test Codes	
	Asset Trace Variables	
	System Config	
	Bluetooth Favourites	
	User Admin >	**Preferences**
		Chance User
		Change Password
		User Profile
	Memory Options	
	Restore Factory Settings	
About		

Appendix B IBP Interconnect cable wiring diagram



Appendix C Temperature cable wiring diagram